Contraceptive and Reproductive Health Technologies Research and Utilization Program

CRTU
Cooperative Agreement
GPO-A-00-05-00022-00
April 29, 2005
through
June 30, 2006

CTR
Cooperative Agreement
CCP-A-00-95-00022-02

September 1, 2005
through
August 31, 2006

Annual Report

with Activity Updates for the CTR No-Cost Extension

USAID FROM THE AMERICAN PEOPLE

fhi Family Health International

Submitted to:
Office of Population and Reproductive Health
Research Technology and Utilization Division
United States Agency for International Development

ANNUAL REPORT

April 29, 2005 – June 30, 2006

Contraceptive and Reproductive Health Technologies Research and Utilization Program

Cooperative Agreement
GPO-A-00-05-00022-00

Contraceptive Technology and Family Planning Research Program

Cooperative Agreement
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Submitted to:
Office of Population and Reproductive Health
Research Technology and Utilization Division
United States Agency for International Development

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ACRONYM LIST

A

AACE	-	Association for the Advancement of Computing in Education
AALA	-	American Association for Laboratory Accreditation
AEs	-	Adverse Events
AFRO	-	Africa Regional Office (FHI)
AIBIR	-	Academia de Investigación en Biología de la Reproducción (México)
AMH	-	Association Medicale Haitienne (Haiti)
AMKENI	-	FHI subproject (from a Swahili word meaning coming together)
AMREF	-	African Medical and Research Foundation and Japanese International Cooperative Agency
APHA	-	American Public Health Association
APHIA	-	Population and Health Integrated Assistance Project
APLAFA	-	Asociación Panameña para el Planeamiento de la Familia
APPRENDE	-	Asociación Para La PRevención de Embarazos No DEeseados
APROFAM	-	Asociación Pro-Bienestar de la Familia (Guatemala)
ARH	-	Adolescent Reproductive Health
ARFH	-	Association for Reproductive and Family Health
ARHP	-	Association of Reproductive Health Professionals
ARV	-	Antiretroviral
ASA	-	American Statistical Association
ASHE	-	Ashe Caribbean Performing Arts Ensemble and Academy
ASHONPLAFA	-	Family Planning Association of Honduras
ASTM	-	American Society for Testing Materials

B

BASS	-	Behavioral and Social Sciences (FHI Group)
BCC	-	Behavior, Change and Communication
BCI	-	Behavior, Change Intervention
BIOS	-	Biostatistics (FHI group)
BMC	-	BioMed Central
BSG	-	Bharat Scouts and Guides Association
BSS	-	Behavioral Surveillance Survey

C

CAs	-	Cooperating Agencies
CBD	-	Community Based Distribution
CBHW	-	Community-based Health Workers
CBRH	-	Community Based Reproductive Health
CDC	-	Centers for Disease Control
CEDPA	-	Center for Development and Population Activities
CEMICAMP	-	Center for Mothers and Infants (Brazil)
CEMOPLAF	-	Centros Médicos de Orientación y Planificación Familiar (Ecuador)
CFAR	-	Center for AIDS Research
CFHC	-	California Family Health Council
CHP	-	Care and Health Program
CMC	-	Chemistry, Manufacturing and Control
COC	-	Combined Oral Contraceptive
COE	-	Center of Excellence
CONRAD	-	Contraceptive Research and Development Program
COPHIA	-	(a USAID-funded Pathfinder project in Kenya)
CRAS	-	Centralized Randomization Database System
CRD	-	Clinical Research Department (FHI Group)
CRF	-	Case Report Form
CS	-	Cellulose Sulfate
CSW	-	Commercial Sex Workers
CT	-	Chlamydia
CRTU	-	Contraceptive and Reproductive Health Technologies Research and Utilization
CTR	-	Contraceptive Technology and Family Planning Research
CTU	-	Contraceptive Technology Update
CV	-	Contingent Valuation

D

DAIDS	-	Division of Acquired Immunodeficiency Syndrome
DCFs	-	Data Collection Forms
DFID	-	Department for International Development
DHMT	-	District Health Management Teams
DMC	-	Data Monitoring Committee
DMPA	-	Depot Medroxyprogesterone Acetate
DMT	-	Decision Making Tool
DMU	-	Dual Method Use
DOH	-	Department of Health
DP	-	Dual Protection
DPU	-	Dual Purpose Use
DRH	-	Division of Reproductive Health (Kenya MOH)
DSA	-	Development Studies Associates
DSFC	-	Division Sante Familiale et Communautaire (Mali)
DSMB	-	Data Safety Monitoring Board

E

ECP	-	Emergency Contraceptive Pills
ECPG	-	Essential Care Practice Guides
EECMY	-	Ethiopian Evangelical Church Mekane Yesus
EFCF	-	Egyptian Fertility Care Foundation
EFCS	-	Egyptian Fertility Care Society
EIS	-	Electronic Information System
EPHA	-	Ethiopian Public Health Association
EPT	-	Evaluation Preparation Team
ERB	-	Ethics Review Board
ERC	-	Ethics Review Committee (Ethiopia)
ESA	-	East South Africa
EVMS	-	Eastern Virginia Medical School

F

FC	-	Female Condom
FCCIT	-	Female Condom Community Intervention Trial
FCI	-	Family Care International
FCO	-	Final Cost Objective
FECASOG	-	Central American Federation of Ob-Gyns (Guatemala)
FGAE	-	Family Guidance Association of Ethiopia
FGC/FGM	-	Female Genital Cutting/Female Genital Manipulation
FGD	-	Focus Group Discussion
FHI	-	Family Health International
FITS	-	Field, Information and Training Programs (FHI group formerly PRU)
FLASOG	-	Federación Latino Americano De Sociedades De Obstetricia y Ginecología (El Salvador)
FLE	-	Family Life Education
FP	-	Family Planning

G

GC	-	Gonorrhea
GCP	-	Good Clinical Practices
GHRD	-	Global Health Research Database
GHS	-	Ghana Health Service
GLP	-	Good Laboratory Practice
GMP	-	Good Manufacturing Practices
GTZ	-	German Technical Cooperation

H

HBC	-	Home Based Care
HC	-	Hormonal Contraceptive
HFLE	-	Health and Family Life Education
HMGN	-	Her Majesty's Government of Nepal
HMSC	-	Health Ministry Steering Committee (India)
HOPE	-	HOPE Enterprises Ltd.
HPV	-	Human Papilloma Virus
HRM	-	Human Resource Management
HSR	-	Health Services Research (FHI group)
HSRC	-	Human Science Research Council

I

IBP	-	Implementing Best Practices
ICAAP	-	International Conference on AIDS in Asia and the Pacific
ICASA	-	International Conference on AIDS & STIs in Africa
ICMR	-	Indian Council of Medical Research
ICRH	-	International Center for Reproductive Health
ICRW	-	International Center for Research on Women
IDE	-	Investigational Device Exemption
IEC	-	Information, Education and Communication
IGWG	-	Interagency Gender Working Group
IMPACT	-	Implementing AIDS Prevention and Control Activities (FHI project)
IMSS	-	Instituto Mexicano de Seguro Social
IND	-	Investigational New Drug Exemption
INTRAH	-	Program for International Training and Health
IPAS	-	International Projects Assistance Services
IPPF	-	International Planned Parenthood Federation
IRB	-	Institutional Review Board
IRESCO	-	Institut de Recherche et des Etudes de Comportements
IRH	-	Institute for Reproductive Health, Georgetown
ISO	-	International Standards Organization
ISSTDR	-	International Society for STD Research (Cameroon)
IT	-	Information Technology (FHI Group)
IUD	-	Intrauterine Device
IWC	-	Integration Working Committee (Zimbabwe)
IWG	-	Interdepartmental Working Group

J

JHPIEGO	-	Johns Hopkins Program for International Education in Reproductive Health
JHU	-	Johns Hopkins University
JICA	-	Japanese International Cooperation Agency
JPPM	-	Joint Program Planning Meeting
JWG	-	Joint Working Group

K

KATH	-	Komfo Anoky Teching Hospital
KZN	-	KwaZulu Natal

L

LAM	-	Lactational Amenorrhea Method
LMIS	-	Logistics Management Information System
LNG	-	Levonorgestrel

M

M&E	-	Monitoring and Evaluation
MAQ	-	Maximizing Access and Quality
MEXFAM	-	Mexico Family Planning Organization
MINSA	-	Ministry of Health Nurses Association (Nicaragua)
MOE	-	Ministry of Education
MOH	-	Ministry of Health
MOHP	-	Ministry of Health and Population
MOPH	-	Ministry of Public Health
MOU	-	Memorandum of Understanding
MRC	-	Medical Research Council (South Africa)
MSH	-	Management Sciences for Health
MSIE	-	Marie Stopes International (Ethiopia)
MSS	-	Management Support Services (Nepal)

N

N-9	-	Nonoxynol-9
NACID	-	Nazareth Children's Center and Integrated Development
NAFDAC	-	National Agency for Food and Drug Control (Nigeria)
NARI	-	National AIDS Research Institute
NASCOP	-	National AIDS & STDs Control Program
NAYA	-	Nepal Adolescent and Young Adult Project
NDOH	-	National Department of Health (South Africa)
NFCC	-	Nepal Fertility Care Center
NFPB	-	National Family Planning Board (Jamaica)
NGO	-	Nongovernmental Organization
NIAID	-	National Institute for Allergic and Infectious Diseases (NIH)
NICHD	-	National Institute of Child Health & Human Development
NIH	-	National Institutes of Health
NIMR	-	Nigerian Institute of Medical Research
NMIMR	-	Noguchi Memorial Institute for Medical Research (Ghana)
NSV	-	No-scalpel Vasectomy
NYAM	-	New York Academy of Medicine

O

OD	-	Organizational Development
OR	-	FRONTIERS Operations Research Agreement
OTC	-	Over The Counter
OVC	-	Orphans and Vulnerable Children

P

PAA	-	Population Association of America
PAHO	-	Pan American Health Organization
PAI	-	Population Action International
PAL	-	Preliminary Approval Letter
PAR	-	Participative Action Research
PATH	-	Program for Appropriate Technology for Health
PCS	-	Population Communication Services
PEPFAR	-	President’s Emergency Plan for AIDS Relief
PFA	-	Patient Flow Analysis
PGI	-	Post-Graduate Medical Research Institute
PHMT	-	Provincial Health Management Team
PHMWG	-	Population and Health Materials Working Group

PHSC	-	Protection of Human Subjects Committee (FHI's IRB)
PI	-	Principal Investigator
PID	-	Pelvic Inflammatory Disease
PLA	-	Participatory Learning and Action
PMA	-	Premarket Approval Application
PMPA	-	Phosphonylmethoxypropyl adenine
PMTCT	-	Prevention of Mother To Child Transmission
PNC	-	Pre-Natal Care
PQC	-	Product Quality and Compliance (FHI group)
PRB	-	Population Reference Bureau
PROFAMILIA	-	Asociación Dominicana Pro Bienestar de la Familia, Inc. (IPPF affiliate in Colombia)
PSA	-	Prostate-Specific Antigen/Project Support Association (S. Africa)
PSI	-	Population Services International
PSS	-	Polystyrene Sulfonate Gel
PVO	-	Private Voluntary Organization

Q

QA	-	Quality Assurance
QAP	-	Quality Assurance Project (Latin America)
QOC	-	Quality of Care

R

R&D	-	Research and Development
RA/QA	-	Regulatory Affairs and Quality Assurance (FHI group)
RCT	-	Randomized Controlled Trial
REDSO	-	Regional Development and Support Office
RETC	-	Research Ethics Training Curriculum
RH	-	Reproductive Health
RHR	-	Department of Reproductive Health and Research
RHRU	-	Reproductive Health Research Unit (South Africa)
RTI	-	Reproductive Tract Infection

S

SA	-	South Africa
SAGO	-	Society of African Gynecologists and Obstetricians (Senegal)
SARA	-	Support for Analysis and Research in Africa
SDP	-	Service Delivery Point
SDM	-	Standard Days Method
SMC	-	Social Marketing Company (Bangladesh)
SOP	-	Standard Operating Procedures

SOTA	-	State Of The Art
SOW	-	Scope of Work
STC	-	Society for Technical Communication
STD	-	Sexually Transmitted Disease
STI	-	Sexually Transmitted Infections

T

TA	-	Technical Assistance
TBD	-	To Be Determined
TBS	-	Tanzania Bureau of Standards
TMs	-	Technical Monitors
TOC	-	Technical Oversight Committee
TOT	-	Training of Trainers

U

UAP	-	Uplifting Adolescents Project
UCH	-	University College Hospital (Ibadan, Nigeria)
UNC	-	University of North Carolina
UNFPA	-	United National Population Fund
URC	-	University Research Corporation
USAID	-	U.S. Agency for International Development
USFDA	-	United States Food and Drug Administration

V

VA	-	Virtual Access (Ghana)
VCT	-	Voluntary Counseling and Testing

W

WHO	-	World Health Organization
WITs	-	University of Witwatersrand
WSP	-	Women's Studies Project (former FHI Project and Group)
WTP	-	Willingness-to-Pay

Y

YCs	-	Youth Counselors

Z

ZNFPC	-	Zimbabwe National Family Planning Council

GLOSSARY

The following table provides key terms that are used in the individual subproject reports:

Collaborating Agency:	A USAID cooperating agency (CA), a private or governmental group, or a nongovernmental organization (NGO) with which FHI is working in partnership. Such agencies provide additional technical or financial support to the subproject (e.g. providing related training or funding local costs). CAs that fund FHI directly for an effort are cited as the funding source, not as a "collaborating agency" on the subproject.
Final Cost Objective (FCO):	The accounting number assigned by FHI's Contracts and Grants Office. It indicates a specific source of funding for a particular subproject. This is the key unit for all financial reports.
Subgrantee:	Institution(s) or organization(s) designated by FHI as responsible for executing some or all of the activities described in the subproject. A Subagreement generally exists between FHI and the named party. In past FHI reports, the term "implementing agency" was used in the same manner.
Subproject:	An activity within the Cooperative Agreement that has specific objectives and outputs. A subproject is generally related to only one FCO number. Multiple FCO numbers are necessary, however, if multiple funding sources are involved. Examples of subprojects are individual clinical trials, survey research studies, workshops or training efforts, major publications and regulatory or management support.
Total Approved Budget:	The most recently approved life-of-FCO or life-of-subproject budget. A subproject's total budget may be supported by one or more FCOs, depending on the number of funding sources. Subprojects often span more than one fiscal year. Therefore, a subproject's total approved budget figure is likely to be greater than the budget cited for any one year.

INTRODUCTION

The Contraceptive and Reproductive Health Technologies Research and Utilization (CRTU) Program is a five-year, $125 million cooperative agreement between USAID and Family Health International (FHI) that was awarded on April 29, 2005. This agreement builds on more than three decades of FHI's experience and accomplishments in contraceptive technology and reproductive health research to advance and support USAID's family planning and reproductive health programs worldwide. The purpose of the cooperative agreement is to increase the range of available choices and the use of safe, effective, acceptable, and affordable contraceptive methods and reproductive health technologies, including microbicides, delivered through high-quality family planning and reproductive health services in developing countries.

This Annual Report provides a comprehensive picture of 90 subprojects that were fully or partially funded by the CRTU for the July 1, 2005–June 30, 2006 reporting period. It is important to note that while the award was received as of April 29, 2005, spending did not begin until July 2005 due to completion of the Contraceptive Technology and Family Planning Research (CTR) Cooperative Agreement. This 10-year agreement was scheduled to end on August 30, 2005. However, a no-cost extension was granted through August 31, 2006 to complete several activities, many of them funded with HIV/AIDS funds. Fourteen subproject reports for these CTR activities are included herein. The final annual report for the CTR was presented to USAID in November 2005. A summary CTR End-of-Project report will also be submitted to USAID under a separate cover.

In light of this transition from the CTR to the CRTU, activity reports for both are included here. However, programmatic and financial reporting references for these two awards differ. The reporting of CRTU-funded activities includes the July 2005-June 2006 time period, while progress updates on the last CTR activities funded through the no-cost extension references the Sept 1, 2005-August 31, 2006 period. As of August 31, 2006, all CTR-funded have been completed and closed. All financial information in this report, however, is specific to the CRTU program. Financial data for CTR activities ongoing during this time frame will be included an End-of-CTR financial report to be submitted in November. Publication information presented in this report includes all CTR and CRTU papers and other writings published and reported to FHI's Library between July 1, 2005 and June 30, 2006. The report of CRTU travel undertaken between July 2005 and June 2006 has been submitted to USAID separately.

FHI's Institutional Capacity and Networks for Management of the CRTU Program

Through FHI's stated mission "to improve lives, knowledge and understanding worldwide…," FHI has forged an alliance with US-based non-profits active within the international arena and country-based resources to facilitate achievement of this mission. This section provides some highlights of achievements in these important areas of work.

Strategic Partnerships

Partnerships are an essential component of FHI's work, and vital to meeting our CRTU research and research utilization outcomes. We have longstanding, well-established, partnerships with many organizations, and continually seek to strengthen existing partnerships and explore new ones. Our strong alliances with governmental agencies, international nongovernmental organizations, universities, and local groups are vital to undertaking high quality research and enhancing the utilization and scale-up of research results to improve programs.

Under the CRTU, FHI has further defined our collaborations through Memorandums of Understanding (MoUs) with eight organizations: Adventist Development & Relief Agency International (ADRA), Contraceptive Research and Development Program (CONRAD), EngenderHealth's ACQUIRE Project, Johns Hopkins University's Center for Communication Programs/INFO Project, Management Sciences for Health (MSH), Program for Appropriate Technology in Health (PATH), Population Council, and Save the Children USA.

Year one of the CRTU's partnership work has focused on establishing internal systems for managing, monitoring, and documenting MoU partner activities. FHI assigned an institutional point person for each MoU partner who is tasked with managing the various aspects of the MoU relationship, including documenting ongoing activities, soliciting MoU partner input into the CRTU's priority setting process, and introducing new ideas or opportunities with the MoU partner. Furthermore, FHI has finalized MoU implementation strategies with five partners, to guide collaborations for the 2006-07 workplan and beyond. Currently, there are over 35 ongoing or planned activities with these eight MoU partners, and several others with non-MoU strategic partners. Key accomplishments for 2005-06 include:

- FHI and EngenderHealth/ACQUIRE co-organized an inter-agency meeting on contraceptive continuation; several research needs were identified and two concept proposals were funded in FHI's 2006-07 workplan. They are: "Assessing and improving service delivery performance of community-based distribution of DMPA in Uganda"and "Development and evaluation of a campaign to increase continuation of hormonal contraceptive methods".
- ADRA worked with FHI on a needs assessment in Madagascar, one result of which has been a demonstration project on CBD of injectables for 2006-07. ADRA will select sites and assist FHI and the local bilateral, SantéNet, with implementation.
- FHI and Save the Children have partnered to scale up CBD of injectables in Uganda. In order to support Save the Children's efforts to expand the intervention to two new districts, FHI is developing and implementing an advocacy campaign.
- PATH coordinated a global consultation on the female condom, bringing together key stakeholders from around the world to review evidence of the female condom's effectiveness in preventing pregnancy and sexually transmitted infections (STIs) and to learn about countries' program experiences. FHI was part of the advisory committee that helped plan the event and assisted to develop and implement a communications strategy. (Please reference FCO 113100: Global Consultation on the Female Condom for the results of this meeting.)

Challenges inherent with partner collaborations include synchronizing planning cycles for joint activities, aligning priorities, and building familiarity and trust at the institutional level. During Year Two of the CRTU, FHI will work to further solidify and expand successful collaborations by placing greater emphasis on joint planning and coordination with USAID to align organizational priorities. As well, FHI's new CRTU Indicators and accompanying Indicator Database will be used to further document research utilization accomplishments with MoU (and other) partners.

Country Programs

In an effort to affect change at the country level and improve the health status of individuals, FHI is focusing resources and activities in four countries under the CRTU. Our in-country presence in the focus countries will be expanded to facilitate the formation of strategic partnerships and networks. This approach ensures that our research and technical assistance activities respond to global, country/regional and local needs.

Year one of the CRTU focused on creating the conceptual framework to guide the implementation of the enhanced country program, building buy-in for the new approach within FHI, developing criteria for focus country selection, and negotiating with missions, stakeholders and partners in short-listed countries. As a result of these activities, four focus countries were secured: Kenya, South Africa, Uganda and Madagascar. Moreover, needs assessments were conducted in all countries via a variety of methodologies that identified specific reproductive health needs. Goals for the focus countries were then articulated based on the identified needs. They include:

- **HIV and Contraceptive Services** (South Africa, Kenya and Uganda) - To increase access, improve quality and expand use of contraceptives to prevent unintended pregnancy among people with, or at high risk of, HIV.
- **LAPMs** (Kenya, Uganda and Madagascar) - To promote feasible, evidence-based models for revitalizing under-used LAPMs and/or introducing new LAPMs.
- **Hormonal Methods** (Kenya, Uganda and Madagascar) - To improve uptake, continuation rates and use patterns of existing hormonal contraceptives.
- **All methods/Cross-Cutting** (All countries) – Overall quality and reach of FP services strengthened.

In response to the defined goals and specific needs in each country, TA and research activities were developed that map back to CRTU outcomes and research to practice priorities. Lastly, internal systems for managing, monitoring, and documenting activities with in-country collaborators were created.

Discussion of CRTU Strategy Areas

The CRTU program, aims to achieve three intermediate results:

- Improved and new contraceptive and reproductive health technologies developed, evaluated and approved;
- Microbicides and microbicides/spermicides developed, evaluated and approved; and
- Use of contraceptives, microbicides and reproductive health technologies optimized and expanded.

To achieve these intermediate results, the CRTU program was initially designed with five technical strategies that function to guide the selection and implementation of CRTU activities:

- Barrier Methods (Male and Female)
- HIV/AIDS and Contraceptive Services
- Hormonal Methods
- Long Acting and Permanent Methods; and
- Microbicides

The technical strategies establish research and research utilization priorities, and set forth outcomes to be achieved by the end of the cooperative agreement. These priorities and outcomes are the basis for the CRTU monitoring and evaluation plan.

A sixth category of crosscutting activities support the implementation of activities carried out under the technical strategies, facilitating the 'research to practice' agenda, including a "focused" effort to achieve impact in a few selected countries where the CRTU concentrates resources. In 2005-06, youth and gender-based efforts are also reported under this crosscutting area if the efforts were not also method-specific. In the next year, a youth strategy will be added to encompass a large and growing body of work on youth that does not fit neatly into a contraceptive method oriented strategy. A final category of subprojects, under the heading Technical Support, includes efforts to provide global leadership and address overarching needs of the CRTU such as monitoring and evaluation and regulatory oversight and quality assurance of our research.

Organization of This Report

Highlights of the CRTU Program (July 2005 – June 2006)

This section provides a brief overview of the major areas of investment and selected accomplishments of the CRTU Agreement during the July 2005 to June 2006 reporting year. This section also graphically depicts geographic coverage, fiscal trends and strategic focus over the reporting year.

Annual Report

The main body of this report consists of subproject descriptions summarizing all of FHI/NC's program accomplishments (July 2005 – June 2006) under the CRTU Cooperative Agreement. The document includes qualitative reports for each subproject funded, fully or partially, by this program. It also includes subproject reports for all CTR-funded activities active during the September 2005-August 2006 period, which represents the final reporting cycle for CTR-funded activities. This report is organized by strategy headings. Within the strategy areas, an effort has been made to group subproject reports in a logical order so those that address similar or sequential objectives appear together. Each subproject description provided in this report includes information on objectives, funding source(s) and total approved budget.

Financial Information

Financial information for all CRTU-funded activities is provided using FHI's internal accounting number or FCO. Expenditures by FCO, for July 1, 2005 – June 30, 2006 are presented in the Financial Information section.

Reference Information

Appendix A includes a list of all articles and other writings published between July 2005- June 2006 with full or partial support of either the CTR or CRTU Program. Because it is often important to know what FHI is doing in any one country or region, a listing is provided (Appendix B) that groups subprojects according to their geographical region and country. A "worldwide" category is used for those subprojects carried out in multiple geographic regions and/or whose clear primary purposes are to have a global impact. Appendix C includes the roster of PQC's Technical Oversight Committee as well as FHI's Board. The work of these executive committees is essential to the successful implementation of our program.

HIGHLIGHTS OF THE CRTU PROGRAM (July 2005 – June 2006)

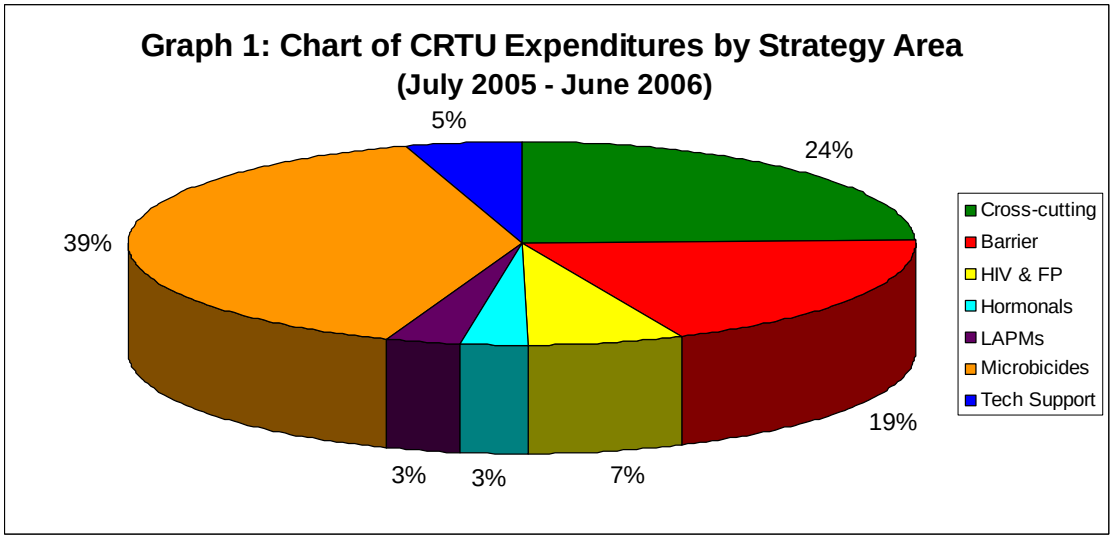
This section summarizes much of FHI's work in relation to the CRTU Program by highlighting efforts during the July 2005 – June 2006 reporting period by both research strategy and geographic region.

Subproject Expenditures by Strategy

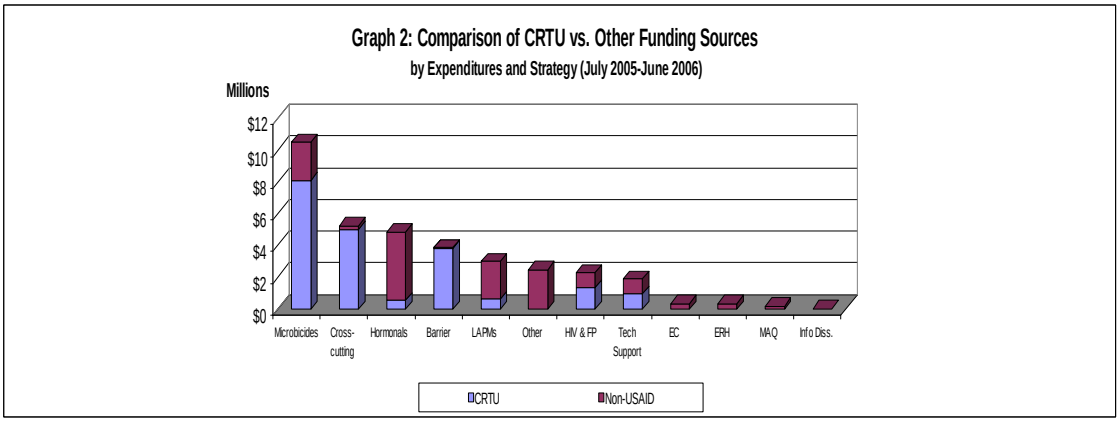
Graph 1 below highlights the areas for strategic investment of all CRTU funds, including core, designated core, field support, PEPFAR, commodities securities and logistics (CSL) and interagency agreement buy-ins. From the graph, we see that microbicides has received the highest level of investment at 39 percent of total funds for the 2005-2006 reporting period. This funding level is consistent with the growth in the microbicides support over the past three years of USAID's investment in contraceptive and reproductive health technology. This trend may continue over the coming years.

The next highest area of investment is the cross-cutting area which received funding at 24 percent of the total CRTU support for the reporting period. This area of work funds activities related to research-to-practice as well as country programs. These research utilization and focus country efforts are intended to facilitate and enhance all other CRTU activities, helping to ensure individually and collectively, the desired outcomes are achieved so that ultimately impact is realized.

Barriers, the second highest funded method area, is the third largest strategy area of investment at 19 percent of expenditures. It is followed by HIV & FP and technical support which were funded at 7 percent and 5 percent of total expenditures, respectively. The long-acting and permanent methods and hormonal method strategies both received 3 percent of CRTU funds.



Graph 2 provides an illustration of the strategic allocation and expenditure of FHI resources for the July 2005 – June 2006 reporting year by showing the distribution of CRTU expenditures in comparison with the expenditure of "other FHI funding sources."[1] The graph is ordered to show funding from highest level to the lowest. As in the previous year, the microbicides strategy is the primary area of FHI focus for contraceptive technology and FP research activities both for CRTU funds and other funding sources. FHI's current portfolio of microbicide work is one with over $10 million of investment. The next major area of investment, at $4 million, is HIV and contraceptive services, supported primarily by USAID. This figure includes several activities working towards the achievement of the President's Emergency Program for AIDS Relief. Further support for this disease prevention strategy can be noted in the investment of over $2 million in the barrier methods strategy.



Other noticeable trends observed:

1. The Long-acting and Permanent Methods area is an important contraceptive area from an efficacy as well as a cost perspective, with the majority of FHI funding coming from leveraged resources. As we move forward in this area of work, we will continue to work on

[1] "Other funding sources" may include grants from foundations, other organizations and/or FHI corporate assistance.

the challenges of increased cost efficiency for implant products, while seeking increased uptake of long-term and permanent methods such as the IUD and improved knowledge of the safety and efficacy of non-surgical female sterilization.

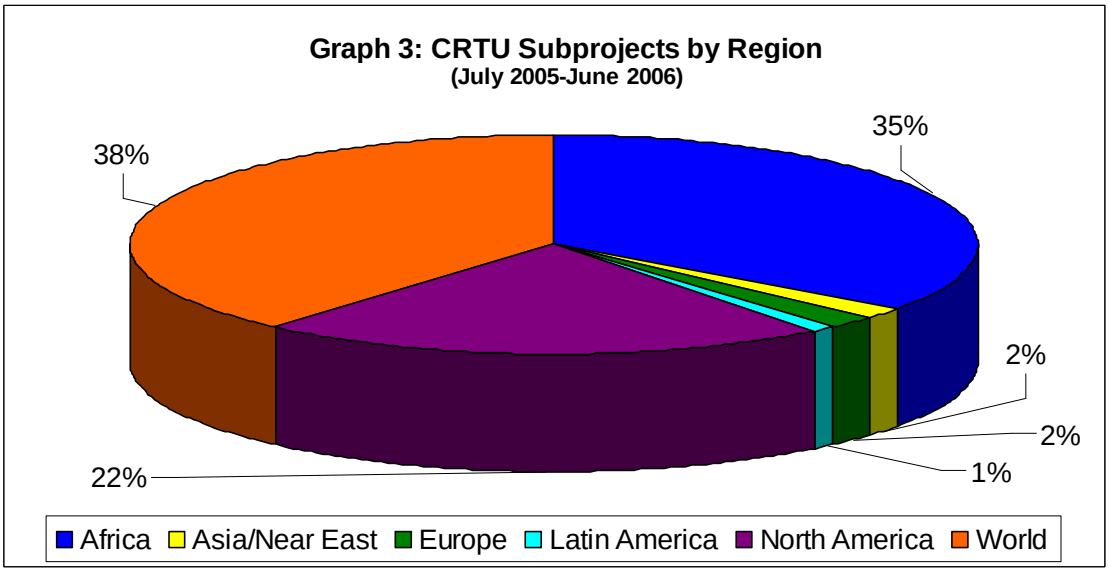
2. During this reporting period, the "Non-USAID, Other" strategy area has included considerable support from Abt Associates for work to increase the private sector's provision of high-quality RH/FP and other health products and services in developing countries. FHI's contribution to this partnership is expertise in all aspects of HIV/AIDS programming, health services research and training programs to improve the delivery of priority health services, operations research and cost effectiveness analysis, behavior change communication, and leadership in current trends and innovations in RH/FP products and services. This area has received about $2 million of investment over this past year.

3. The HIV and Contraceptive Services area has a more even distribution of funding between USAID and other leveraged-funds. This area has about $2 million of investment for the reporting period. Research results in this area are targeted around VCT and FP service integration activities.

4. The technical support area represents important partnership work within FHI and includes CRTU assistance to WHO in RH policy development work. This area has under $2 million of funding.

Subprojects by Geographic Region

The geographic distribution of FHI's Contraceptive and Reproductive Health Technologies and Research Utilization Program between July 1, 2005 and June 30, 2006, is reflected in Graph 3.



From this graph, one can see that the largest proportion (38%) of CRTU-funded subprojects is implemented worldwide. Included in the "worldwide" definition are research studies conducted across multiple countries. The next highest proportion of activities is located in Africa. With much of our focus country program work targeting areas with the greatest need, it is not surprising that over one third of CRTU activities are located in this region. That figure is higher when one

considers than many "worldwide" efforts include activities in or involving Africa. The proportion of subprojects in Asia/Near East, Europe and Latin America continues to remain low under the CRTU, as was true under the CTR. Of the three areas, work in Asia/Near East is most likely to see an increase in funding over the next few years due to increased work in Tier Two focus countries India and Cambodia.

The chart indicates a high proportion (22 percent) of North America-based activities. This figure represents an increase as compared to last year (14 percent). There are a couple of reasons for the high distribution in this region: 1) as the mandate of the CRTU Cooperative Agreement is to develop new and improved contraceptive methods, it is necessary to conduct at least some of the pivotal research in the United States in order to obtain USFDA approval of such methods; and 2) most of the numerous subprojects involving statistics and data management support provided by FHI to CONRAD are included in the count of North America-based subprojects.

Overall, this report represents a summary of FHI's program of work under the Contraceptive and Reproductive Health Technologies and Research Utilization Program. Key results for this reporting period will be summarized in the upcoming Annual Key results reporting process. We acknowledge and appreciate the contributions of USAID and all of our strategic partnerships and country-based collaborating agencies in the achievement of CRTU goals. As stated in our 2006 CRTU Management Review exercise:

> *FHI is well positioned to address the existing implementation and research needs, however, the extent to which they will be able to do so depends greatly on the amount of support they will receive from USAID, and their ability to leverage those resources against other sources (FS, PEPFAR, etc.).*

The hypothesis that diaphragms might offer women some protection against sexually transmitted infections (STIs), including HIV, will soon be tested in several randomized controlled trials... Testing the diaphragm's effectiveness against bacterial STIs was logical because gonorrhea and chlamydial infection are clearly acquired in the cervix and not the vagina. And evidence of the diaphragm's potential to protect against these and other STIs has been accumulating. If the diaphragm does indeed protect the cervix against STIs, it might indirectly protect against HIV, since HIV infection is facilitated by the presence of other STIs.

Network, Vol. 22, No. 2, 2003: Female Barrier Methods

Male condoms—when used consistently and correctly—are an effective means of preventing HIV infection, gonorrhea (in men), and unplanned pregnancy among people who are sexually active and need to protect themselves. Both a consensus report issued by the U.S. National Institutes of Health (NIH) in 2001 and a fact sheet released by the U.S. Centers for Disease Control and Prevention (CDC) in 2002 have recognized these facts.

Network, Vol. 22, No. 4 2003: Barrier Methods

BARRIER METHODS

Strategic Objectives

- To support the development of and evaluate new or modified use of existing products.
- To evaluate the public health impact of introducing barrier methods into reproductive health programs.
- To test approaches for achieving optimal uptake, correct use, and maximum affordability of barrier methods.

FHI/NC subprojects fully or partially funded by USAID's CTR Agreement:

A. Female Barrier Methods

Africa Regional:	Female Condom Information Dissemination (FCO 3429 and previously 9425)
USA:	Phase I Post-Coital Testing and Safety Study of the Modified SILCS Diaphragm (previously FCO 2281)

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

USA:	Pivotal Effectiveness Study of the PATH SILCS Diaphragm (FCO 112101 and previously 2299)
USA:	Next Steps for Clinical Research of New Female Condoms (FCO 112111/132114)
Worldwide:	Global Consultation on Female Condom (FCO 113100)
Worldwide:	Measuring Effectiveness of UNFPA-sponsored Female Condom Promotion Initiatives (FCO 114107)
USA:	Comparative Study of PATH's Soft-Cling Woman's Condom and the Female Condom (FCO 112102 and previously 2287)
USA:	Structural Integrity of the FC2 Female Condom (FCO 112117)
USA:	Formative Research to Determine the Feasibility of Recruitment for "True Efficacy" Trials (FCO 116104)
Worldwide:	International Standards Development (FCO 118100)

B. Male Barrier Methods:

Madagascar:	Evaluating Disinhibition of Condom Use in a Diaphragm Trial (FCO 112115)
South Africa:	ABC Approach for Youth on University Campuses in South Africa (FCO 153101)
Kenya:	Evaluating the "Young Men as Equal Partners" Project (FCO 114100)
Worldwide:	Production Surveillance of Condoms- Domestic and Off-Shore (FCO 148100)

Africa Regional: Female Condom Information Dissemination (FCO 3429 and previously 9425)

Technical Monitor: RNaik

Status: Complete
Group: FITS

Objective(s): 1) To raise awareness and stimulate discussion among health sector decision-makers about the appropriate role of the female condom in reproductive health programs; 2) to support the policy-making process regarding female condom distribution through the provision of succinct, objective information about the method; and 3) to strengthen service delivery of existing female condom programs by distributing up-to-date information and educational materials to program managers.

Description: Through this Africa Bureau-supported initiative, FHI provided policymakers and program planners in Sub-Saharan Africa with information needed to make evidence-based decisions about appropriate incorporation of the female condom into reproductive health services. FHI compiled results from completed research and packaged key findings in a practical format for key audiences, tracked ongoing research studies, and facilitated dissemination of findings as soon as investigators made them available. Partners in sub-Saharan Africa were encouraged to weigh the evidence as they consider the introduction of the female condom into programs. FHI looked for other opportunities to discuss and interpret current research findings with key researchers, policymakers and program managers similar to the workshop coordinated through this subproject in Winterton, South Africa in August 2001.
An anticipated outcome of this exercise was a consensus statement to be published in an international journal; instead, presentations were made at the USAID Technical Update in December 2001. For countries or programs that have already determined to include the female condom in the method mix, FHI has distributed materials to support service delivery.

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Activities, Accomplishments, Problems through December 31, 2005

- Approval to develop the subproject was obtained in November 2000.
- For additional information, see the RY'03 Annual Report.
- FHI distributed the Female Condom materials to international conferences including: African Women's Health Conference February 2003 (S. Africa), SAGO January 2003 (Mali), CTU March 2003 (DC) and to all FHI Country Offices in June 2003.
- FHI collaborated with the Population Council to prepare and contribute written material for publication of a special issue of the Quality/Calidad/Qualite. A new FCO was created for this activity (FCO 3298).
- A summary report for the subproject was completed in September 2003. The final report was entitled, "Female Condom Information Dissemination: FHI Research Briefs on Female Condom Numbers 1-7".
- Research Brief No. 3 "Can the Female Condom be Used More than Once Safely?" was updated in July 2003 to reflect current WHO information regarding re-use. The revision was posted to the FHI Web site and is available in hard copy format.
- The revised No. 3 brief was translated into French and Spanish and printed for dissemination.
- The total number of information packets distributed during the life of the subproject was 8200 English, 1350 Spanish, and 1700 French.
- A total of 392 information packets were distributed July 2003-June 2004. Ongoing distribution of materials for routine requests will be made possible via FHI general dissemination funds.
- The summary report of the subproject was submitted to the Africa Bureau; however, staff transitions contributed to a delay in its completion.

- Talking points were added to the research briefs in the female condom information packets.
- Translation of talking points into French and Spanish was put on hold due to the fact that the female condom research briefs are no longer being distributed.
- The remaining funds in this subproject were used to support presentation of the results of the Madagascar female condom trial at the July 2005 meeting of the International Society for Sexually Transmitted Disease Research.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The remaining funds were utilized to help fund the end of project (CTR) report.

Findings and Outcomes:

- Findings from the 2001 needs assessment revealed that decision-makers desire information on re-use, cost and the impact of gender relations on use. Respondents expressed interest in having a forum where pilot projects and experiences could be shared.
- Participants at the August 2001 South Africa conference were interested in the female condom in a plenary session involving providers, users, donors, program planners, and peer educators.
- Presentations at the USAID Technical Update in December 2001 summarized findings in technical and field areas, synthesizing research conducted over the last five years. These efforts were undertaken in lieu of the planned consensus statement to be published in an international journal.
- Presentations at the Global Health Council Annual Conference (May 2002), and the Gender, Health, and Poverty Conference in Dakar, Senegal (June 2002), and the International Society for Sexually Transmitted Diseases Research meeting (July 2005) attest to the interest and demand for female condom information and strategies for information dissemination by national-level policymakers and public health workers alike.
- Findings from FHI's small reader's survey in August 2002 with participants in sub-Saharan Africa indicated that overall, respondents reported that the printed materials were very useful and that they were able to share their copies with an average of over 30 additional readers.
- The Federal Ministry of Health of Nigeria requested the female condom packets be used in their formal launch of the product in November 2002.
- The total number of information packets distributed during the life of the subproject was 8200 English, 1350 Spanish, and 1700 French.
- Analysis of hits on the FHI Web site for the female condom topics page from January to March 2002 indicates more than 1000 hits on the English "frequently asked questions," 1400 hits on a Spanish Network article, and 650 hits on the French Network article on female condoms.
- Ten health information listervs, appropriate for receipt of the FHI female condom information, picked up the announcement for distribution on their lists. The approximate readership of those lists is 18,370 people.

Funding Source(s):		USAID - US Agency for International Development/Field Support		**FCO Approved:**	**9425**	Nov 2000
					3429	Jun 2001
Total Approved Budget:	**9425**			**Projected End Date:**		Jun 2006
	3429	$	Reassigned FCO 200,000			

USA: Phase I Post-Coital Testing and Safety Study of the Modified SILCS Diaphragm (previously FCO 2281)

Technical Monitor: GPittman
Collaborating Agency(s): CONRAD
Status: Complete
Group: CRD

Objective(s): To provide statistical analysis and data management support to a CONRAD study to compare the effectiveness of the SILCS diaphragm (prototype VI) used with Gynol II ® (2% nonoxynol-9) to baseline cycle results and the SILCS diaphragm used with KY Jelly® to baseline cycle results in preventing sperm from penetrating midcycle cervical mucus.

NOTE: The approval of protocol amendment #3 (March 2004) added two objectives: 1) to assess the handling and fit of the polymer spring SILCS diaphragm (modified prototype VI) in volunteers with failed clinical fitting with the SILCS diaphragm (prototype VI); 2) to compare the effectiveness of the polymer spring SILCS diaphragm (modified prototype VI) used with Gynol II (2% nonoxynol-9) to baseline cycle results in preventing sperm from penetrating midcycle cervical mucus.

Description: This was a multi-center, single-blinded, randomized, Phase I study in 40 healthy, sexually active women with regular menstrual cycles who had undergone bilateral tubal ligation or salpingectomy.

Participation in the study lasted approximately four months. Each participant underwent three post-coital tests (PCT), one in each of three consecutive menstrual cycles. The first post-coital test was a baseline test done without the use of any product. Subsequently, post-coital tests were carried out during the second and third menstrual cycle using either the SILCS diaphragm with Gynol II or the SILCS diaphragm with KY Jelly. Product acceptability was assessed by evaluating questionnaires completed by participants after each post-coital test. Male partners of study participants were also consented to participate in this study.

NOTE: At the direction of protocol amendment #3, women who completed the study (i.e., completed a baseline and two test cycles) were asked to come back for a third test cycle using the polymer spring SILCS diaphragm (modified prototype VI) with Gynol II (2% nonoxynol-9).

NOTE: FHI provided data management and statistical analysis support to CONRAD for this study.

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Activities, Accomplishments, Problems through December 31, 2005

- The protocol was approved by CONRAD and FHI team members in March 2003.
- The protocol underwent major revisions based on comments received from participating sites, and was amended in May 2003.
- Approval to proceed with the development and implementation of this subproject was received from USAID in May 2003.
- Case report forms were finalized, printed and shipped to CONRAD in July 2003.
- Recruitment began in July 2003 with 38 out of expected 40 women enrolled by December 2003.
- CRFs were annotated and a data entry protocol established.
- Plans for data management, monitoring, and statistical analysis were completed.
- Error specifications were written and validation of the error checking programming begun.
- Recruitment was completed in spring 2004 with 40 participants enrolled.

- Protocol Amendment #3, dated March 9, 2004, was approved by local site IRBs and implemented at the sites.
- Table shells were drafted, and the analysis plan was updated to incorporate the data gathered for Amendment #3.
- All data were received in-house in May 2005.
- All data entry and querying was completed and the final data freeze was made in June 2005.
- The final statistical report was sent to CONRAD in July 2005.
- FHI finalized study documentation.
- The FCO was closed in August 2005. (Any FHI review of CONRAD's final clinical report or manuscript, and archival of study documents will be charged to BIOS support under FCO 112100).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- CONRAD received approval for a poster presentation at the ACOG meeting in May 2006.

Findings and Outcomes:

- Both the SILCS diaphragm (metal or polymer spring) with N-9 reduced the average number of progressively motile sperm per high power field (HPF) from a baseline of 12.5 to zero. The SILCS diaphragm (metal spring) with K-Y reduced the number of progressively motile sperm per HPF to 0.5.
- Results from this PCT indicate that the current SILCS diaphragm design with the polymer spring and used with N-9 performed well and is acceptable for contraceptive effectiveness testing. The less expensive polymer spring which is easier to manufacture will replace the metal spring found in standard diaphragms.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	May 2003
Total Approved Budget:	$ 129,977	**Projected End Date:**	Aug 2005

USA: Pivotal Effectiveness Study of the PATH SILCS Diaphragm (FCO 112101 and previously 2299)

Technical Monitor: HKiernan
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: At least one promising new diaphragm evaluated for contraceptive effectiveness and/or prevention of sexually transmitted infections (STI)

Objective(s): To provide data management, statistical analysis, regulatory audits, and monitoring of half of the sites for this pivotal study designed to assess the safety of the SILCS diaphragm and its effectiveness in preventing pregnancy.

Description: This CONRAD multi-center, single-arm contraceptive effectiveness study of SILCS diaphragm used with 2% N-9 will assess and compare the contraceptive effectiveness of the SILCS diaphragm with that from women who received the Ortho All-Flex® diaphragm in the FemCap and diaphragm pivotal study (historical controls). In this study, approximately 440

women at risk for pregnancy with no contraindications to the use of a diaphragm will be recruited at six study sites in the USA. To the extent possible, sites will be selected among those centers which participated in the FemCap and Diaphragm study (FHI Study #7823). Each participant will agree to use the SILCS diaphragm with 2% N-9 as her only method of contraception for 28 weeks.

In addition, FHI is providing support to a substudy. Of the 440 women in the main study, 40 (20 at each of 2 sites) women will be recruited for a substudy collecting colposcopy and microflora specimen data. Women in the substudy will be randomized to receive either the SILCS diaphragm or the Ortho All-Flex diaphragm (concurrent controls). This substudy is needed for the following reasons: 1) progress made in colposcopy makes it difficult to collect data comparable to the historical control group; and 2) there is a lack of data for microflora evaluation in the historical control group. In order to facilitate the planned historical control analysis, the substudy design and data collection methods will conform to that of the FemCap/diaphragm pivotal study (historical control).

FHI is responsible for data management, statistical analysis, sharing of monitoring responsibilities, and regulatory audits for the main study and substudy.

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Activities, Accomplishments, Problems through December 31, 2005

- FCO 2299 was assigned under the CTR Agreement in July 2005. Given the timing of the submission for 2299, (July - only 1 month) prior to the close of CTR, no preliminary approval was requested, rather approval to implement was requested and obtained from USAID on August 11, 2005.
- Later in July 2005, FCO 112101 was assigned under the new CRTU Agreement in anticipation of the pending close of the CTR Agreement.
- FCO 2299 was closed in August 2005.
- FHI biostatistical staff and key CONRAD staff attended a pre-IDE meeting with the USFDA in August 2005.
- FHI received a protocol synopsis from CONRAD in September 2005.
- A draft protocol was received in November 2005.
- The first team meeting took place with CONRAD via conference call in November 2005.
- Study sites were identified by CONRAD and include: EVMS, Norfolk, Virginia; Magee-Womens Hospital, Pittsburgh, Pennsylvania; Johns Hopkins University, Baltimore, Maryland; UPENN, Philadelphia, Pennsylvania; Baylor College of Medicine, Houston Texas; and CFHC, Los Angeles, California.
- A Memorandum of Understanding was completed and signed by FHI and CONRAD in November 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- An Approval to Implement letter for FCO 112101 was submitted to USAID in January 2006; approval was received in March 2006.
- Joint teleconferences between FHI and CONRAD team members began in February 2006.
- The Investigators Meeting was held in May 2006.
- The FHI clinical monitor began developing the study manual and regulatory binder.
- The monitoring plan and protocol were approved in June 2006.
- The team began CRF development.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved:**	**2299**	Jul 2005
				112101	Jul 2005
Total Approved Budget:	**2299**	$ 19,805	**Projected End Date:**		Jun 2008
	112101	$ 1,092,437			
		$ 1,112,242			

USA: Next Steps for Clinical Research of New Female Condoms (FCO 112111/132114)

Technical Monitor: CJoanis
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: At least two lower cost female condom models assessed for safety, effectiveness, and acceptability

Objective(s): To facilitate: (1) the completion of a plan of action to take to the FDA to determine regulatory approval paths for the three new female condom (FC) types; (2) the selection of the best candidate(s) FCs to move through the regulatory process; (3) quality assurance testing and assembly of clinical supplies for the CONRAD-sponsored study of two lengths of the Reddy FC; and (4) the provision of biostatistical input into the development of international standards for FC products.

Description: Providing female condoms for pregnancy and HIV prevention is a priority for USAID. Reality® (FC1), approved by the FDA in 1993, is sold globally, but sales are limited by its high price. A goal of USAID is to develop a low-cost FC equivalent to FC1. The three condoms studied in this subproject are: FC2, Reddy 6, and the PATH Woman's Condom. The subproject will cover four areas: (1) Strategy for and discussions with the FDA: Preliminary discussions will be held and possibly a meeting with the FDA to develop a strategy for clinical studies of FCs and regulatory paths for each FC type. (2) Assembly of clinical supplies and QA testing of the Reddy 90mm and 120mm devices (CONRAD sponsored): The PQC will test the condoms for water leakage, air burst, tensile strength, dimensions, and package integrity. After testing, the FCs and other clinical supplies will be assembled and shipped to Pune, India. (3) Research: This study will be conducted in South Africa. This study will pinpoint slight variations in user preference and device performance of the three condom types. In this study, surveys and methods will be more market-specific compared to previous FC studies. Participation will include 180 women who will use five of each FC and complete an interviewer-assisted survey after using each type. After using all three FC types, the participants will enter Phase II of the study. In Phase II, participants will select the FC(s) of their choice (unlimited access) to use for about three months. Volume and preference for FCs will be recorded. In Phase III of the study, about 36 participants will be asked to take part in interviews to determine reasons for preference of a particular device. (4) Support at ISO: An FHI biostatistician will attend meetings of the ISO Female Condom Working Group to provide input in the development of international manufacturing standards for female condoms.

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Activities, Accomplishments, Problems through December 31, 2005

- Earlier research on the new female condoms was completed under the previous Cooperative Agreement with USAID (reference FCO# 2286).
- In September 2005, an FHI biostatistician attended the ISO Female Condom Working Group meeting held in Berlin.
- Also in September 2005, an organization and planning teleconference was held with CONRAD and USAID. This meeting provided guidance for the development of the FC strategy.
- In October 2005, a meeting was held at FHI with USAID to finalize the study design for the comparative study of the FC2, Reddy, and PATH Women's Condom.
- The protocol outline for the comparative study of the three female condoms was completed in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The study site was selected and the Principal Investigator accepted the study. The PI is Mags Beksinska from the Reproductive Health and HIV Research Unit (RHRU), Witswatersrand University, Durban, South Africa.
- The study protocol was written and submitted to the PHSC in May 2006. The PHSC approved the study with minor modifications.
- We began the draft and compilation of the Investigators Manual in May 2006.
- The study questionnaires were drafted and submitted to the PI and BIOS for preliminary review (June 2006).
- Clinical supplies for the CONRAD sponsored Reddy 6 study were assembled and sent to the PI in Pune, India in June 2006.
- The subagreement for the RHRU was drafted in June 2006 and is in review at FHI.
- During the year, we continued to support the development of ISO standards for female condoms through teleconferences and technical consultations as required.
- Study products for FC2 and PATH were ordered in June 2006.
- A Clinical Agreement between FHI and PATH was drafted in June 2006.

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/Microbicides	**FCO Approved:**	**112111**	Aug 2005
				132114	Jun 2006
Total Approved Budget:	**12111**	$ 350,000	**Projected End Date:**		Aug 2007
	132114	$ 631,947			
		$ 981,947			

Worldwide: Global Consultation on Female Condom (FCO 113100)

Technical Monitor: KShears

Status: Complete
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based counseling approaches for male and female condom promotion incorporated into family planning service guidelines, including those used by HIV/AIDS programs (VCT, ART, PMTCT) in up to six countries. Evidence regarding the effectiveness of female barrier methods disseminated to policy makers to influence procurement and programming decisions.

Objective(s): To synthesize current research on the female condom and work with CRTU partners to disseminate this information to help decision-makers determine the appropriate role for the female condom in RH programs.

Description: The female condom is intended to serve a dual role, offering protection from pregnancy and STI. Many women's advocates and policy-makers see the female condom as a new alternative that women can use to better protect themselves against HIV/STIs. However, program managers in health systems remain cautious about committing to wide-scale introduction of the method, in large part due to questions about cost effectiveness.
This subproject supported planning for and participation in the Global Consultation on the Female Condom (GCFC). An important motivation for five FHI staff to participate in the GCFC was to get guidance on the CRTU research agenda by hearing the priority information needs of decision makers. Through this participation, FHI researchers helped guide interpretation of existing evidence and received guidance on what additional evidence is needed about the method.
The subproject built on the female condom dissemination effort undertaken by FHI in 2000-2002 with support from USAID's Africa Bureau, which included an information needs assessment among African program planners, a research briefs series, sessions on the female condom at numerous technical conferences, and a broad campaign of electronic information dissemination.
The September 2005 Consultation in Baltimore, which this subproject used as a venue for results dissemination and partnership-building for in-country dissemination, offered an "opening" to inform commodities decisions, policymaking, and –indirectly– the information environment in which women in developing countries make method choice decisions.
The conference, and a limited number of research-to-practice-to-research follow-on activities, including a dissemination meeting in Madagascar where CTR research was presented, served as a venue to disseminate current research on the female condom to program decision-makers to help them determine the appropriate role for the female condom in RH programs.

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Activities, Accomplishments, Problems through December 31, 2005

- In September 2005, five FHI staff participated in the Global Consultation on the Female Condom. J. Smith moderated a review of female condom research findings, with a presentation by T. Hatzell.
- Hatzell drafted an action plan for advancing female condom (FC) research/program implementation.
- B. Robinson and K. Shears worked with PATH and UNFPA to develop/implement a GCFC communications strategy. Robinson and Shears also reviewed a PATH/UNFPA press release that was distributed to donors, CAs, and listservs.

- PATH, UNFPA and FHI worked with the INFO Project to organize an online forum around the major themes of the consultation, and FHI publicized it through listservs.
- Hatzell helped to implement the action plan. In December 2005, Hatzell proposed FHI could lead the design and implementation of M&E of FC programming. FHI was also proposed to lead cost analyses and operations research on re-use.
- FHI's research summary on FC reuse was updated and posted on the FHI Web site in 2005. The initial plan to update, print, and distribute all FHI's FC research summaries was revised to take advantage of opportunities for further collaboration with GCFC partners to develop a concept proposal for a Women's Prevention Initiative and disseminate findings from the GCFC.
- Hatzell participated in an October 2005 meeting in Madagascar to disseminate findings of the male and female condom study in that country. A summary of the research was completed and translated into French for distribution.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on April 4, 2006.
- Hatzell worked with colleagues on the GCFC steering committee to develop a Letter of Intent to study the introduction of women-initiated HIV prevention methods that was submitted to the Bill & Melinda Gates Foundation for funding.
- Hatzell collaborated with other presenters from the GCFC to prepare an editorial for a special reproductive health issue of The Lancet. The article was declined by Lancet, but will be revised and submitted to another journal.
- Hatzell and Shears reviewed a draft synthesis of information from the GCFC to be published by PATH in July 2006 and disseminated to donors and policy-makers.
- The FCO was closed on August 31, 2006.

Findings and Outcomes:

- A session presenting female condom research evidence was delivered at the September 2005 Female Condom Global Consultation. Over 100 reproductive health program managers, policy makers, donors and researchers attended the consultation.
- A workshop was delivered to approximately 80 health professionals in Madagascar, including national policy makers from the National AIDS Committee, the Ministry of Health and Family Planning, and the National Institute of Public and Community Health. Methods and findings of FHI's male and female condom study were presented and discussed, raising awareness of needs concerning reproductive health services targeting populations at high risk for HIV/STI.
- FHI's technical and editorial review of "Female Condom: A Powerful Tool for Protection" strengthened this document, which is a synthesis of information from the Global Consultation on the Female Condom that will be distributed to donors and policy-makers beginning July 2006.
- A Letter of Intent for a Women's Prevention Initiative, including FHI-led monitoring and evaluation of programs to introduce female condoms and other women-initiated STI and pregnancy prevention methods, was submitted to the Bill & Melinda Gates Foundation.
- Members of the GCFC steering committee have cited FHI's fact sheets as an important resource because they are the only concise syntheses of information about the female condom available in three languages.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Aug 2005
Total Approved Budget:	$ 65,754	**Projected End Date:**	Jun 2006

Worldwide: Measuring Effectiveness of UNFPA-sponsored Female Condom Promotion Initiatives (FCO 114107)

Technical Monitor: THoke
Collaborating Agency(s): UNFPA
Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Feasibility, cost, and effectiveness of alternative male and female condom distribution mechanisms assessed

Objective(s): 1) To collaborate with UNFPA in developing a protocol for measuring the relative cost-effectiveness of alternative female condom distribution systems; and 2) to devise a plan for UNFPA-funded technical assistance in M&E.

Description: UNFPA is currently launching an initiative in 22 countries worldwide to strengthen country capacity to introduce or re-introduce female condom programming. Countries will have the latitude to position female condom distribution according to their own needs and resources; it is anticipated that distribution will take a variety of forms within public- and NGO-sponsored family planning, HIV/AIDS, and STI programs. UNFPA's multi-country initiative creates an opportunity for FHI to assess the feasibility, cost, and effectiveness of alternative female condom distribution mechanisms. Through this subproject, which supports study design, FHI will gather information about the spectrum of UNFPA-supported female condom programs in order to select sites and devise a technically sound protocol for an investigation of the relative cost-effectiveness of alternative distribution models. Data to be gathered in the protocol development phase will focus on issues such as: the objectives, scope, and scale of distribution programs in different countries; possible mechanisms for monitoring female condom distribution at the central level and uptake at the facility level; possibilities for assessing changes in dual protection behaviors in response to female condom promotion; opportunities for collecting cost data; willingness of country partners to collaborate on this assessment; and the information needs of national and international decision-makers relative to female condom distribution models. Based on this data, FHI will prepare a protocol for a comparative assessment of female condom distribution programs, to be initiated in Year 2 of the CRTU.
Additionally, UNFPA has indicated funds are likely to be available in Year 2 to support FHI technical assistance (TA) for country-level monitoring and evaluation of male and female condom distribution programs. This subproject will support the development of FHI's plan for offering such TA.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The technical monitor joined UNFPA, PATH, and BMGF partners in preparing a Letter of Intent (LOI) submitted to the Bill and Melinda Gates Foundation. The proposed project would measure the effect of female condom promotion in up to four countries, as a means of laying the path for future HIV-prevention technologies like microbicides. In May 2006, BMGF advised the team to resubmit the LOI to present a scaled-down project.
- The technical monitor contributed to a proposal submitted in May 2006 to the Danish government for a $2 million project supporting male and female condom programming. FHI was proposed to lead M&E for this multi-country subproject.

Funding Source(s): USAID - US Agency for International
FCO Approved: Sep 2005

		Development/Core		
Total Approved Budget:	$	30,303	**Projected End Date:**	Jun 2007

USA: Comparative Study of PATH's Soft-Cling Woman's Condom and the Female Condom (FCO 112102 and previously 2287)

Technical Monitor: GPittman
Collaborating Agency(s): CONRAD
Status: Complete
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: At least two lower cost female condom models assessed for safety, effectiveness, and acceptability

Objective(s): To provide statistical and data management support to a CONRAD study designed to assess the functional performance, safety and acceptability of the PATH Woman's Condom (WC) compared to the Reality Female Condom (FC).

Description: This was a Phase I, comparative, crossover study done at three domestic sites with a substudy conducted at one of the sites using colposcopic assessment. Recruitment included 75 couples at low risk for STIs and protected against pregnancy through use of reliable (non-barrier) contraceptive methods. Couples were to maintain monogamous relationships for 3 months prior to enrollment and throughout the study. The couples were randomized to a female condom sequence (WC/FC or FC/WC). At all sites, couples used 4 condoms of each type at home in 4 acts of intercourse over a 2-4 week period. After a follow-up visit, the procedures were repeated with the second condom type.

At one site (n=25), one condom of each type was used for fit assessment, a baseline colposcopy was performed, and each condom type was used with simulated intercourse followed by colposcopic evaluation.

NOTE: In December 2004, the protocol was amended to change the colposcopy substudy. It was discovered that simulated intercourse posed technical problems during testing, and actual intercourse was to be used instead. The amendment also included a baseline colposcopy done prior to the first condom use of each of the 2 condom types. The couples used the condom for the first act of intercourse within 72 hours of the baseline colposcopy; and the female participant returned for a follow-up colposcopy within 6 hours of intercourse.

NOTE: FHI provided statistical and data management support for this CONRAD study funded by USAID Core funds.

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Activities, Accomplishments, Problems through December 31, 2005

- The protocol was reviewed and approved in August 2004.
- The CRFs were reviewed, approved, and printed in fall 2004.
- The data management plan was reviewed and approved, and the data management system was set up.
- The Investigators Meeting was held in November 2004.

- Enrollment began in December 2004.
- The protocol was amended in December 2004 to change the conduct of the colposcopy substudy.
- CRFs were changed for the substudy (due to the amendment in December 2004).
- The data management set-up was completed and entry and querying began in April 2005.
- The table shells and the analysis plan were developed and circulated for review.
- Recruitment for the main study ended in May 2005.
- CTR FCO 2287 was closed in August 2005, and FCO 112102 was established with funding under the new CRTU Cooperative Agreement.
- Participant follow-up for the colposcopy substudy ended in August 2005.
- The sites were closed in August 2005.
- In August 2005, CONRAD requested some descriptive stats regarding the acceptability of PATH WC and FC.
- All data were received in-house at FHI in September 2005.
- An interim statistical report was completed at CONRAD's request in September 2005.
- In November 2005, a problem was noted in the number of condom breaks reported which led to the need for resolution of query issues and some recoding by CONRAD prior to completing the final data freeze.
- The final data freeze was completed in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI completed a manual review of the questionnaires to ensure that no administrative issues impacted endpoints.
- Analysis was completed, and the statistical report was sent to CONRAD in January 2006.
- FHI reviewed the final clinical report and manuscript, as requested.
- The study was archived, and FCO 112102 was closed on June 30, 2006.

Findings and Outcomes:

- Results are still considered confidential by PATH. Findings are being used in development of the USAID-funded pivotal comparison study of female condoms.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved:** **2287**	May 2004
			112102	Jul 2005
Total Approved Budget: **2287**	$	100,201	**Projected End Date:**	Jun 2006
112102	$	47,658		
	$	147,859		

USA: Structural Integrity of the FC2 Female Condom (FCO 112117)

Technical Monitor: CJoanis

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Research necessary to effect policy change and acceptance of female condom reuse among providers and local governments completed, with results incorporated into policies and service delivery guidelines

Objective(s): To determine the feasibility of reusing the new FC2 female condom. This subproject will compare the test values obtained at baseline and after each wash/bleach sequence (1X, 2X, etc.) with the manufacturer's specifications for water leakage, tensile strength, and air burst testing.

Description: A prototype female condom (FC2), made of synthetic latex and meeting the same structural specifications as the polyurethane female condom (FC1), has been developed by the Female Health Company. The major advantage of FC2 over its predecessor is cost, ~$0.60 vs. $0.74, respectively (public sector pricing). While FC2 will be less expensive than FC1, its projected public sector price is still 15 times the cost of a male latex condom. In relation to its indication for one-time use, donors may still be reluctant to supply the device.

Given the successes shown in cleaning FC1 and the fact that the FC2 device is still more expensive than a male latex condom, there is a need to study the reuse potential of this new FC. Since the FC2 material is a proprietary polymer, there is no published information, and no research has been conducted to assess the impact of detergents and disinfectants on the structural performance of the material. Such information may be used to provide guidance on cleaning the FC and result in the provision of an FC product that can be cost-competitive with male condoms. Findings will be presented along with other recently completed FC research to members of the WHO panel on FC reuse. Depending on results, new guidance may have to be written concerning FC reuse when the FC2 becomes more widely available.

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Activities, Accomplishments, Problems through December 31, 2005

- The first draft of the protocol was completed in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The study product was ordered from the Female Health Company in March 2006.
- The protocol was finalized and approved in April 2006.
- Baseline and structural testing was completed at the PQC in June 2006.
- The testing report was completed by the PQC in June 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 35,000	**Projected End Date:**	Oct 2006

USA: Formative Research to Determine the Feasibility of Recruitment for "True Efficacy" Trials (FCO 116104)

Technical Monitor: ACorneli
Collaborating Agency(s): University of North Carolina, Chapel Hill
Status: Ongoing
Group: BASS

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated

Objective(s): To identify characteristics of women who are most likely to participate in a one-month, placebo/no method-controlled contraceptive efficacy or effectiveness trial; and to develop strategies to recruit women willing to join the study.

Description: This research will be implemented in two phases at both the U.S. and Madagascar sites: a formative phase and a mock trial phase. The first phase includes approximately 25 interviews with community stakeholders others in a position to provide information about the local culture and 12 focus group discussions with potential participants. In this phase, we will: 1) identify characteristics of women who are most likely willing to participate in the trial (previous research has targeted women who actively desire pregnancy but who are willing to delay conception for one month and women who are willing to accept pregnancy but are not necessarily actively trying to conceive); and 2) develop culturally appropriate recruitment strategies directed at the women identified.

The second phase of the research will proceed only if data from the first phase suggests that recruitment of the identified population is possible. In the second phase, strategies will be implemented for a limited period of time and women will be interviewed who respond to determine whether or not they would be willing to enroll in a trial, what aspects of the recruitment strategy and trial design they find acceptable and problematic, and what suggestions they have for improvement of the study approach. The recruitment approach will be amended based on the data collected, in an iterative fashion. The aim is to arrive at a recruitment method and trial design that is likely to yield acceptable enrollment and follow-up rates, which can be used in the development of an actual trial.

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Activities, Accomplishments, Problems through December 31, 2005

- Approval for a scaled-down version of the original study was received from USAID on December 9, 2005.
- Study preparatory activities began in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The protocol, data collection instruments, and consent forms were developed for the U.S. site.
- Discussions with collaborators from a possible additional site were carried out (Durban, South Africa). Funding would be supplemented from another source, if approved.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 300,000	**Projected End Date:**	Mar 2008

Madagascar: Evaluating Disinhibition of Condom Use in a Diaphragm Trial (FCO 112115)

Technical Monitor: MSteiner

Status: Canceled
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: Innovative research methodologies that produce more valid information about sexual behavior and barrier method use for programmatic decision making developed and validated

Objective(s): To assess the potential of "condom migration" by comparing the proportion of participants with biological evidence of recent unprotected intercourse (i.e. PSA positive) at the screening visit, the enrollment visit and at least three follow-up visits.

Description: With any hierarchical approach to HIV/STI prevention, clients may substitute more effective methods with less effective methods. In diaphragm studies, researchers are concerned that condom use may decrease after participants have been enrolled due to a sense of protection offered by the diaphragm. Countering this concern, several studies suggest that sexual risk-taking behavior decreases during trial participation. However, such studies assess "condom migration" through self-reported measures, and self-reports of condom use are often inaccurate because of the social desirability to over-report condom use once enrolled into a trial.

This subproject, planned as an ancillary study to the STI CTG (FCO 12090) diaphragm trial in Madagascar, would have collected vaginal swabs at screening, enrollment, and at least three follow-up visits to test for PSA from a random sample of 400 participants. A module of detailed questions to assess the number of coital acts and condom use during the previous two days was to be included. If the proportion of participant specimens had shown evidence of PSA remains constant from the screening visit to the end of the study, this would suggest that disinhibition is not a major concern. If the proportion showing evidence of PSA had increased, this would suggest disinhibition in the trial through lower condom use and/or a higher coital frequency. If the proportion showing evidence of PSA decreased, this would suggest participants are engaging in safer sex by using more condoms and/or a lower coital frequency.

Data from the ancillary study will be combined with the qualitative data collected as part of the parent study looking at disinhibition and condom migration.

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Activities, Accomplishments, Problems through December 31, 2005

- The protocol and questionnaire were drafted in October 2005.
- The approval to implement letter was sent to USAID and subsequently rejected in November 2005. USAID suggested attempting funding through the microbicide strategy funding stream.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Funding from the microbicides fund account was not granted. As a result, the study was canceled.

Findings and Outcomes:

- This subproject was canceled due to lack of interest from USAID. A similar study is being implemented with CDC funding at Dr. Padian's MIRA diaphragm site in Zimbabwe.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 150,000	**Projected End Date:**	Jun 2006

South Africa: ABC Approach for Youth on University Campuses in South Africa (FCO 153101)

Technical Monitor: CJagemann
Collaborating Agency(s): Association of Catholic Tertiary Students (ACTS); The South African Center for Organizational Development (SACORD)

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Cost and effectiveness of alternative ABC delivery models targeting youth (including communication channels, messages, parental/adult involvement, community support, and collaborating partners) evaluated and applied in at least three countries

Objective(s): To inform university students about specific risks for HIV/STIs and unintended pregnancy and to educate them in specific life skills to help them adopt ABC behaviors.

Description: Students on four university campuses – the University of the Western Cape; University of the Free State, Qwa Qwa Campus; University of Venda, and University of Limpopo, Medunsa Campus – will be reached through two major components: media outreach and mentorship by peer educators. The media outreach component consists of a five-episode radio series to be developed based on focus group discussions with students on reproductive health and risks for STIs and HIV/AIDS, and on abstinence and being faithful to protect one's health. The second part of the intervention will build directly on the messaging from the radio series. Small groups will be formed to listen to and discuss the radio program. The small groups will be facilitated by peer educators who will be responsible for addressing students' knowledge and skills associated with AB behaviors. Young adults represent the segment of the South African population with the fastest growing rates for HIV and unintended pregnancies. By focusing interventions where young men and women naturally congregate, interventions can be tailored to their needs with the aim of reducing their risks.

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Activities, Accomplishments, Problems through December 31, 2005

- Three universities were selected to participate in the subproject based on need of the student population, institutional ability to provide programmatic oversight and supervision and geographic proximity to other participating universities. The participating universities include; University of the Western Cape: University of the Free State, Qwaqwa campus; and the University of Limpopo, Medunsa campus.
- Twenty-six peer educators were recruited on each campus to participate in the program. All peer educators received a basic training in peer education skills.
- Two workshops were held with the University staff, who supervises the peer educators, in order to review and adapt life skills curricula used by other organizations such as the Peace Corps and Hope Worldwide, among others. The objective of the curriculum was to give young people the enhanced skills needed to adopt abstinence and being faithful as protective behaviors against HIV/STIs and unintended pregnancies.
- A small group of university students attended one of the workshops and provided feedback that was incorporated in the curricula. UNFPA supported this effort by providing a facilitator for the workshops. This facilitator also provided some curricula development work.
- Local training experts were identified to review and comment on the life skills curriculum prior to implementation. These training experts then facilitated the Life Skills training that was held in December 2005 for all peer educators. This training was organized and facilitated by SACORD. A supervision structure was established wherein the peer educators will meet bi-weekly with their supervisor in an assigned supervision group of thirteen (13) peer educators. Supervisors will use the qualitative data on the content of the BCC groups to facilitate these sessions. The university staff person who provides the supervision will receive monthly supervision via telephone with the technical monitor.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Training for peer educators on life skills has continued on each campus, exploring the topics covered in the curriculum in greater depth. Additional training topics such as team building, successful recruitment and journaling have been covered.
- Supervision of peer educators has continued on an individual and group basis.
- Peer educators have played a key role in student orientations on each of the campuses; providing information on the ABC approach and answering questions and concerns about STIs/HIV and unintended pregnancy.
- A four part radio series, “The ABC Lifestyle on Campus” was produced and aired on community radio stations with a reach of 3,793,000 listeners.
- The University of the Free State has secured regular, weekly air time for their ABC project on the local Qwaqwa station.
- A presentation by a peer educator from University of the Free State was made to the Life Skills program of the Department of Social Justice. As a result of the presentation on the ABC projects’ Life Skills curriculum, the Department has asked the university to partner with them on their life skills programme.
- Peer educators at the University of the Western Cape assisted in the planning and took an active part in a major VCT campaign in April. A total of 400 students were counseled and tested over the two days of the campaign. In May, a special meeting was convened on the Medunsa campus of Limpopo University with the peer educators and other students interested in becoming peer educators. Information was given to the students about the ABC project. Students gave input to attending FHI staff (Director, Sonja Martin FHI/S.A. and Wendy Castro from FHI, NC) on how the program can be improved on the Medunsa campus. These suggestions are being implemented, and include stronger communication and better logistical planning for informational meetings.

Findings and Outcomes:

- The University of Venda withdrew their participation in the intervention in December 2005 due to conflicting priorities within the university. Reports from the stations on the radio series have all been positive. A typical comment; “This morning I received the Series 'The ABC Lifestyle on Campus.' How refreshing and needed in the whole of South Africa. A suggestion, maybe a copy to the Health Minister or even to our President." (Radio 786). Several stations have suggested that the series be translated into local languages.
- Scheduling regular BCC group meetings around the university calendars has proven to be difficult. As an alternative, holding a series of six-weekly meetings, instead of an on-going meeting schedule throughout a semester will be considered at the closing meeting for this phase of the subproject to be held in September.
- Although funding is not in place for FY 06, each program has a plan of action to continue most activities until FY 07 funds can be secured.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	Aug 2005
Total Approved Budget:	$ 200,000	**Projected End Date:**	Sep 2006

Kenya: Evaluating the "Young Men as Equal Partners" Project (FCO 114100)

Technical Monitor: SThomsen
Collaborating Agency(s): Family Planning Association of Kenya; Swedish Institute for Sexuality Education (RFSU); Family Planning Association of Uganda (FPAU); Health Communication Partnership/Uganda (JHU)

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Approaches for overcoming male resistance to male condom use, informed in part by “exemplars” who succeed in using condoms more often than the norm, documented and replicated

Objective(s): To measure change among young men 10-24 years of age after the implementation of the Young Men as Equal Partners subproject in the following indicators: 1) sexual and reproductive health knowledge and attitudes; 2) attitudes towards gender equity; and 3) sexual and reproductive health behaviors.

Description: Current efforts to slow the rapid spread of HIV/AIDS in Eastern and Southern Africa include heavy investments in educating youth on the dangers of HIV/AIDS through peer education, and school and health facility-based programs. However, despite frequent calls for more male involvement in such programs, little is known about how programs for young men should look, and what works best.

The Swedish Association for Sexuality Education (RFSU), in association with the Family Planning Associations of Kenya (FPAK) and Uganda (FPAU), is implementing a program entitled “Young

Men as Equal Partners." The primary goal of the subproject is to sensitize, train and support young men aged 10-24 to act as role models in sexual and reproductive health and on gender issues within their community, and to advocate for male involvement in society at large. The subproject has three major modes of communication: young male peer educators, trained male schoolteachers, and trained service providers in sexual and reproductive health (SRH). The target group of the intervention is young men aged 10-24 years. FHI will evaluate the effectiveness of the RFSU-supported intervention.
The study will use a pre/post-test design. Household surveys of young men will take place at baseline and two years after the initiation of the intervention, in order to determine the impact of the intervention. An extra district will be surveyed in Uganda in order to provide a baseline measurement for the Health Communication Partnership's assessment of the "Be a Man" media intervention. The study will include a process and cost evaluation. The results of this evaluation should provide guidance for the program planners and policymakers in East Africa on the effectiveness of male sexuality education on improving the sexual attitudes and behaviors of youth.

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Activities, Accomplishments, Problems through December 31, 2005

- The technical monitor conducted site visits in September and October 2005.
- The study protocol was approved by both PHSC and the Kenyan IRB in November 2005.
- Data collection instruments were pre-tested and 24 enumerators were trained in Kenya in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Baseline data were collected in Kenya and Uganda from January to March 2006.
- An analysis plan was developed and approved in February 2006.
- Baseline tables were developed and shared with collaborating organizations in May and June 2006.
- A database with baseline data was provided to the Health Communication Partnership in Uganda in June 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Aug 2005
Total Approved Budget:	$ 492,000	**Projected End Date:**	Aug 2008

Worldwide: Production Surveillance of Condoms- Domestic and Off-Shore (FCO 148100)

Technical Monitor: SHamel

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Production surveillance and compliance testing routinely conducted and capacity expanded to support offshore procurement of products used in family planning and HIV/AIDS prevention programs

Objective(s): To ensure pre-distribution quality of condoms procured domestically and offshore by USAID for developing country programs.

Description: This program began in 1990 to provide close scrutiny of condom production and to ensure that condoms, procured domestically and distributed to developing countries by USAID, meet all performance standards. In 2005, the program was extended to include condoms procured from offshore factories. One hundred percent of production lots are evaluated for acceptance prior to distribution, and factories are periodically inspected for adherence to GMPs and USAID contract requirements. This subproject tracks payments for contracted sampling services including reimbursements to the manufacturers for samples taken for quality testing. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCOs 8015 Condom Production Surveillance and 8018 Production Surveillance Sampling).

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Activities, Accomplishments, Problems through December 31, 2005

- Over 500 production lots produced by domestic suppliers and 300 production lots from offshore suppliers were evaluated and released for distribution.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Two new offshore condom contracts were awarded in March, 2006. Surveillance activities included a pre-qualification audit of one new supplier.
- Beginning in June 2006, condoms for USAID programs will be produced in China, along with Korea and the USA.

Funding Source(s):	USAID - US Agency for International Development/Field Support	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

When used correctly and consistently, oral contraceptives (OCs) are among the most effective reversible methods of contraception. But reported pregnancy rates during the first year of OC use are as high as 32 percent. Because a major contributing factor to these OC "failures" is thought to be missed pills, researche are trying to determine how women's daily routines, interpretations of pill taking, or knowledge about OCs affects their pill use. Such information is needed so that family planning programs can help clients take OC more consistently.

Network, Vol 22, No. 3, 2003: Hormonal Contraceptive Methods

HORMONAL CONTRACEPTIVES

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Nicaragua:	RCT of Quick Start vs. Advance Provision of COCs: Bleeding and Continuation (FCO 2274/112109 and previously 1351/1383)
TBD:	Continuous vs. Cyclic Use of COC Pills (FCO 112118)
Uganda:	Promoting DMPA Provision by Community Health Providers (FCO 113108)
Uganda:	Improving Service Delivery of CBD of DMPA (FCO 11411)
South Africa:	Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI (FCO 112119)
South Africa:	Improving Continuation Rates for Injectable Contraceptives (FCO 114102)
India:	Discontinuation of DMPA among Private Sector Clients (FCO 12031/114110)
Nicaragua:	Improving Continuation Rates for Injectable Contraceptives (FCO 114113)
USA:	Contraceptive Discontinuation: Setting the CTRTU Research Agenda (FCO 113102)
Worldwide:	Pregnancy Provider Checklist & Reference Guide 2005 Update & Implementation (FCO 113107)

Nicaragua: RCT of Quick Start vs. Advance Provision of COCs: Bleeding and Continuation (FCO 2274/112109 and previously 1351/1383)

Technical Monitor: KNanda

Status: Complete
Group: CRD

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated

Objective(s): 1) To determine if the "Quick Start" approach leads to higher continuation rates than advance provision of COCs over the six-month duration of the study; and 2) to determine if bleeding patterns for those subjects given COCs immediately (Quick Start) are not worse than in those subjects given COCs to start at their next menses onset (Advance Provision).

Description: This study enrolled 230 women who presented to a family planning clinic requesting COCs, who were not pregnant, had no contraindications to oral contraceptive pills, and had a menstrual period within the past month, but were not in the first week of the menstrual cycle. The women were randomly assigned to one of two groups. Each woman in the "delay" (i.e., Advance Provision) group was given three packs of pills and instructed to take the first pill on the day her next period begins. She was advised to use abstinence or a barrier-contraceptive method until she takes the first pill. Each woman in the "immediate" (i.e., Quick Start) group was given three packs of pills and told to take the first pill immediately and to use barrier methods for the first seven days. All women were followed for six months to assess study outcomes, including the proportion who start pills, duration of pill use, and bleeding patterns and complaints.

NOTE: Additional funding for this subproject was provided by the Hewlett Foundation (FCOs 1351 and 1383).

2005—06 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2005

- A preliminary approval letter was submitted to USAID in June 2002 and was signed by USAID in November 2002.
- The study team was selected, and initial planning meetings were held.
- The PHSC approved the protocol in February 2003.
- Site evaluation took some time in order to find a site that met the following desired specifications: low travel cost to the site, the site was on the list of priority countries, the site had a high OC prevalence, the site required OC users to see a provider to get pills, and the site would allow minors to receive pills without parental consent.
- Staff conducted site-evaluation visits, negotiated budgets, and sub-contracted PROFAMILIA located in Managua, Nicaragua.
- Staff finalized data collection forms, the monitoring plan, and data management plan.
- The study was initiated at PROFAMILIA in Managua, in October 2003, and recruitment began shortly thereafter.
- Monitoring visits were conducted in spring and fall of 2004.
- Enrollment and follow-up were completed in early June 2005.

- A site close-out visit was conducted in late June 2005.
- The data management activities were completed.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006
- Data analysis was completed in May 2006.
- Data were accepted and presented as a poster presentation at the American College of Obstetricians and Gynecologists Annual meeting held in May 2006.
- FHI staff began working on a manuscript.

Findings and Outcomes:
- FHI worked successfully with a new site, PROFAMILIA in Managua, to do this study.
- Ninety-two percent of women completed the 6-month study. Kaplan-Meier pill continuation probabilities were high and similar in both groups (quick start 0.97, advance provision-0.98, log-rank *P* -,65). When analyzed by intent-to-treat, the total number of bleeding/spotting days per trimester was also similar. However, 10 women randomized to advance provision began combination OC's immediately, and 9 women started combination OC's before their next period. When data were analyzed by treatment used, we could not rule out a difference of more than 3 days in total bleeding/spotting days during the first trimester (quick start, n - 127, mean- 12.3; advance provision, n- 84, mean-10.1). Bleeding/spotting days were similar in the second trimester. Other bleeding outcomes were similar, regardless of analysis method. There were no differences in pregnancy rates.
- Based on these results "Quick Start: is a reasonable method of combination OC initiation for developing countries, with high continuation rates despite slightly more bleeding/spotting days initially.

Funding Source(s):			USAID - US Agency for International Development/Core; Hewlett Foundation/Private	**FCO Approved:**	**2274**	Jun 2002
					1351	Aug 2002
					1383	Mar 2004
					112109	Jul 2005
Total Approved Budget:	**2274**	$	250,311	**Projected End Date:**		Aug 2006
	1351	$	100,000			
	1383	$	63,250			
	112109	$	40,480			
		$	454,041			

TBD: Continuous vs. Cyclic Use of COC Pills (FCO 112118)

Technical Monitor: KNanda

Status: In Development
Group: CRD

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated

Objective(s): To evaluate continuation rates, adherence, and acceptability of combined oral contraceptives (COCs) used by the 21/7 cyclic regimen compared with continuous use.

Description: Over 1 million unintended pregnancies annually are related to OC use, misuse or discontinuation. COC discontinuation rates are very high in developing countries, ranging from 16% in Zimbabwe to 52% and 73% in the Dominican Republic and Turkmenistan, respectively. The monthly regimen of 21 active pills followed by 7 inactive pills was created to mimic spontaneous menstrual cycles. However, the 7-day hormone-free interval is associated with withdrawal symptoms including bleeding, pain, breast tenderness, bloating/swelling and headaches. Alternate regimens of oral contraceptive pills, in which the duration of the active pill phase is longer than 21 days and/or the placebo phase is shorter than 7 days, may provide advantages over currently available standard 28-day regimens by reducing symptoms associated with the hormone-free interval, decreasing bleeding (and potentially anemia), enhancing acceptability, and thus improving continuation rates. There are no published data on the use or acceptability of extended use COC regimens in women in developing countries.
This will be a prospective, randomized, controlled clinical trial, to be conducted in a family planning clinic in a developing country. Approximately 400 healthy 16-30 year-old, non-pregnant, and non-lactating women with regular menstrual cycles will be randomized to monophasic COCs (ethinyl estradiol 30 mcg and levonorgestrel 150 mcg) using either the conventional 21/7 regimen or continuous use. Participants in the continuous COC group will use pills continuously unless bleeding or prolonged spotting signals need for a hormone-free interval. We will evaluate pill continuation through 12 months, assess adherence, acceptability (both quantitatively and qualitatively), bleeding, and side effects. Additional outcomes are pill instruction comprehension, 12-month pregnancy probabilities, and hemoglobin levels.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI obtained preliminary approval to work on this study in the 2006 Workplan.
- By December 2005, FHI staff had completed a literature review and begun drafting the protocol. Preliminary contacts were also made with potential sites.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Site evaluation has taken some time to find a site that meets the following desired specifications: low travel cost to the site, the site is on the list of priority countries, the site has a high OC prevalence, the site required OC users to see a provider to get pills.
- The study team was selected in April-May 2006.
- FHI staff conducted a site evaluation visit on Virtual Access in Accra, Ghana in April 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 500,000	**Projected End Date:**	Aug 2007

Uganda: Promoting DMPA Provision by Community Health Providers (FCO 113108)

Technical Monitor: KKrueger
Collaborating Agency(s): Save the Children
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Strategies to enhance uptake of hormonal methods developed and evaluated
Policies and service delivery guidelines will be changed in at least one country to reflect new research findings

Objective(s): 1) To improve the quality of family planning services offered at selected community health programs in Uganda and one other East African country by providing technical assistance for the expansion of contraceptive options to include injectable contraception; 2) to generate interest in scale-up and replication of DMPA provision by community health workers among policy-makers and community health programs throughout the African continent and other regions; 3) to initiate discussions with Ministries of Health in Uganda and one other East African country, which may result in amendment of the National RH Guidelines so that eligibility to provide injections is based upon appropriate training and demonstrated skill; 4) to update FHI's DMPA Checklist in line with the WHO Medical Eligibility Criteria and disseminate it; and 5) to produce and print 500 toolkits or "how-to" guides to enable programs to expand their choice of contraceptive methods to include injectables.

Description: The results of a cohort study conducted by FHI in collaboration with SC the Children/USA (FCO 9327) demonstrate the safety, feasibility, and acceptability of community-based distribution (CBD) in a rural Ugandan district. The study results reinforce the wealth of successful experiences from other regions such as Asia and South America, and provide a strong basis to affirm that well trained community health workers can provide injectable contraception safely in the African context.
Given the reproductive health challenges in the proposed East African countries, improvements in access to and knowledge of contraceptive options, can have a tremendous impact on the reproductive health outcomes of women. In addition since DMPA is a strongly preferred method in the proposed country sites (accounts for over 40 percent of the method mix) and since community health programs remain an important mechanism for contraceptive distribution in the rural areas, the introduction of injectables to this distribution system has the potential to increase demand for DMPA, and substantially increase contraceptive prevalence.
This subproject will involve a multi-tiered approach. First, FHI will strengthen our efforts in Uganda to build consensus, expand provision of DMPA by community health workers, and amend national family planning guidelines. Second, a toolkit will be designed to enable community health programs to expand their choice of contraceptive methods to include injectables. Third, FHI will develop and implement a comprehensive action plan in collaboration with a selected partner in East Africa to implement DMPA service provision in their community health programs. Finally, FHI will disseminate and showcase the toolkit as a means to generate interest and further promote inclusion of DMPA among methods provided by community health workers throughout the African continent and other regions.

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Activities, Accomplishments, Problems through December 31, 2005

- A meeting, "Community-based Provision of Injectables: Current Developments and Collaboration for Action," developed with Save the Children (SC) and JHPIEGO was planned for October 2005. Due to scheduling conflicts, the meeting was postponed until 2006.
- In October 2005, the FHI DMPA Checklist was updated in accordance with WHO's 2004 medical eligibility criteria, and an outline for the Reference Guide for the checklist was developed.
- In October 2005, discussions were initiated with SC regarding the subproject follow-on to the 2005 feasibility and acceptability study (FCO 9327). Also, the Director of Field Programs traveled to Uganda to determine interest for this subproject. USAID/Uganda was reluctant to provide approval until SC received funds to implement the work. The Mission suggested revisiting in January 2006 or as soon as SC received funds.
- In November and December 2005, follow-up was conducted with SC. They received an award letter but funds were not received until May 2006.
- The DMPA checklist was promoted to SC via the menu of practices disseminated in November 2005. In December 2005, a draft dissemination plan for the DMPA checklist was developed.
- Outreach to Kenya and Uganda MOHs, as well as other local stakeholders, to endorse the DMPA checklist was conducted in October and December 2005. In December, representatives of the Kenyan family planning working group conducted a review of the of the checklist to solicit feedback and facilitate endorsement and co-branding by the MoH and to promote local ownership and increase uptake.
- In December 2005, a collection of existing program and research briefs and related materials were compiled to present to the Kenya MOH in an effort to generate interest in replication of DMPA provision by community health workers.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI co-planned the January 2006 inter-agency meeting on CBD of DMPA at JHPIEGO. Twenty-five people participated from INFO, Save the Children, USAID, FHI, Pfizer, and JHPIEGO. The purpose of the meeting was to discuss how to collaborate to get information out about CBD of DMPA, and how to cultivate champions and support change so that this "best practice" is implemented in appropriate programs.
- The inter-agency meeting generated a working group which has convened via conference call quarterly and will continue to operate (supported by FCO 113114).
- Opportunities to promote CBD of DMPA in a second African country were pursued in Malawi, Tanzania, Madagascar, and Kenya, January – June 2006.
- In March 2006, existing research briefs on CBD DMPA were shared with the review committee for the Uganda National FP Guidelines. Also, FHI and SC staff co-presented the 2004 feasibility study findings (FCO 9327) at the AMREF Family Planning 101 workshop in Tanzania. The presentation was well-received by over 40 NGO and PVO participants.
- The ATI was approved in April 2006.
- SC-Uganda received funds for the intervention in late April 2006 and joint planning began in earnest.
- Topics for updated advocacy briefs were reviewed by in-country partners in Kenya and Uganda in April. Draft research and program briefs were written for the advocacy kit in April-May 2006, and the advocacy briefs were shared with in-country reviewers in Kenya and Uganda in June.
- In June 2006, the Kenya MOH registered their interest as the second African country for this subproject. Advocacy activities will be the focus in Kenya.
- The Technical Monitor traveled to Uganda in June to secure buy-in and launch the subproject with SC and the MOH. In addition, partners strategized for a core team meeting in July to include district champions, and plan for an educational tour and a larger stakeholders meeting in early fall.
- Advocacy strategies were drafted for both Kenya and Uganda in June 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 250,000	**Projected End Date:**	Jun 2007

Uganda: Improving Service Delivery of CBD of DMPA (FCO 114111)

Technical Monitor: JBaumgartner

Status: In Development
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated

Objective(s): To assess and improve the service delivery of DMPA in community-based distribution programs with a particular focus on continuation rates.

Description: A recent FHI study conducted in collaboration with Save the Children demonstrated the safety, feasibility and acceptability of community-based distribution (CBD) of depot medroxyprogesterone acetate (DMPA) in a rural Ugandan district. Results showed that CBD provision of DMPA appears to be as safe as provision by nurses. DMPA clients of CBD agents are equally satisfied compared to their clinic-going counterparts and may even prefer CBD provision to clinic-based provision. Given that DMPA is a strongly preferred method in Uganda and that CBD programs serve a broad sector of the population, the introduction of injectables to this distribution system has the potential to increase demand for DMPA and substantially increase contraceptive prevalence particularly in rural areas.
The objective of this research subproject is to assess and improve service delivery performance for community-based distribution of DMPA in Uganda. The feasibility study was an intensive pilot project with significant resources including an enhanced management information system in order to follow up CBD clients. Therefore, more information about provision of DMPA by CBD workers in a more realistic or "day-to-day" implementation setting and timeframe is needed. A key indicator for evaluating service delivery performance of CBD of DMPA compared to the traditional clinic-based model is continuation rates. This research subproject will investigate the implications of CBD worker continuity, location of re-injection, and sex of the CBD worker on continuation rates, among other factors, during CBD scale up efforts in Uganda, which will provide evidence-based guidelines for service provision that supports contraceptive continuation.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Baumgartner met with Save the Children/USA in Uganda in June 2006 to discuss design and protocol development. A meeting with USAID/Uganda was also held to solicit their feedback on the study design.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Feb 2006
Total Approved Budget:	$ 197, 775	**Projected End Date:**	Jun 2008

South Africa: Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI (FCO 112119)

Technical Monitor: ERaymond

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: Critical questions regarding the long term safety and benefit of hormonal contraceptives identified, and at least one high priority question addressed through research

Objective(s): To determine whether or not the proposed randomized trial is feasible, and if so, to develop a plan for implementing the study.

Description: Data from several recent observational studies have suggested that use of progestin-only contraceptive methods may increase the risk of acquisition of sexually transmitted infections (STIs), including chlamydia (CT), gonorrhea (GC), and HIV. However, this conclusion is suspect because of possible failure to control adequately for selection bias and confounding. For example, a higher rate of risky behaviors among progestin-only method users than among non-users could result in an apparent but false association between method use and infection. Considering the public health importance of both progestin-only methods and STIs, clarification of this issue is urgently needed. In addition, the role of herpes simplex virus (HSV) infection in mediating an increased HIV risk associated with depot medroxyprogesterone acetate (DMPA), as suggested in one recent study, needs further evaluation. The best way to provide this clarification would be through a randomized trial. This subproject will support activities aimed at assessing the feasibility of a randomized trial to investigate the effects of DMPA on the incidence of GC and CT and possibly HSV, and if feasible, support the application to other donors for funding to implement the trial. Anticipated activities may include: developing the trial protocol; selecting study sites which will require surveys at multiple locations to assess the feasibility of recruitment and the incidence of GC/CT/HSV in prospective trial populations, and visits to sites that seem promising; and investigating sources of funding for the trial.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Three potential sites were identified, including two in South Africa and one in Jamaica.
- Budgets were negotiated with the South Africa sites, and contracts are in process.
- Budget negotiations continued with the Jamaica site.
- One additional potential site in Madagascar was investigated but dropped because a reasonable budget could not be negotiated.
- Informed consent forms and survey instruments have been drafted and are under review by the site investigators.
- Approval to implement was provided by USAID in June 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 150,000	**Projected End Date:**	Jun 2007

South Africa: Improving Continuation Rates for Injectable Contraceptives (FCO 114102)

Technical Monitor: JBaumgartner

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated

Objective(s): To improve continuation rates for injectable contraceptives by developing and testing an intervention tool for family planning providers that will: 1) reduce the proportion of DMPA/NET-EN clients who discontinue (i.e. do not come back at all); 2) reduce the proportion of DMPA/NET-EN clients who are late for their re-injections; and 3) increase the proportion of late DMPA/NET-EN clients who leave the clinic with a re-injection or another temporary contraceptive method until their next scheduled re-injection.

Description: Injectable contraceptives such as DMPA and NET-EN account for a large proportion of the method mix for women in low resource settings; however, continuation rates are low. In addition to women who choose to discontinue, a proportion of women who are considered "discontinuers", are in fact, women who are actually late for their re-injections. Following up on a previous FHI study in South Africa (FCO 9515), this study will be a prospective cohort study of hormonal injectable users. This study will develop and evaluate a new tool for providers that encourages client continuation and helps ensure re-injections for late clients who would like to continue using injectables. The intervention will be composed of: 1) enhanced counseling by providers for initial injectable clients; and 2) provider training on how to manage late continuing injectable clients.

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Activities, Accomplishments, Problems through December 31, 2005

- The Women's Health Research Unit at the University of Cape Town (UCT) in the Western Cape was identified as the subgrantee in October 2005.
- In October 2005, Baumgartner met with UCT collaborators to discuss the study design and protocol development and with USAID to update them on the study. The basic study design was agreed upon.
- Initial contacts were made with Eastern Cape provincial health officials, who are responsible for public sector service delivery; the goal was to solicit their support and feedback in the design of the study intervention, since scale up will be through the public sector and needs to be sustainable.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The protocol was completed and approved by PHSC in June 2006. Approval to implement was obtained in July 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 496,386	**Projected End Date:**	Jan 2008

India: Discontinuation of DMPA among Private Sector Clients (FCO 12031/114110)

Technical Monitor: KKatz

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated

Objective(s): To estimate the continuation rates for the injectable contraceptive DMPA and compare rates between private sector clinics in the DIMPA network to private sector clinics not in the network. The subobjectives are to: 1) examine client experiences with use of DMPA; and, 2) examine provider provision of DMPA with respect to screening, counseling, follow-up and safe injectable practices.
Note: The original title of this subproject reflected its early roots with the PSP Project: "Abt PSP 1510: Analysis of Costs and Efficiencies of Social Marketing". The title has been changed to reflect a refocusing on continuation issues with DMPA.

Description: Injectable contraceptives such as DMPA account for less than 1% of contraceptive use among women in India mainly due to negative publicity regarding the contraceptive's side effects by women's groups and the subsequent removal of DMPA from the Indian Government's Family Planning Program. Thus, in India, DMPA is provided only in the private sector by DIMPA and non-DIMPA network providers. The DIMPA network is run by the USAID funded PSP-One India organization. DIMPA network members obtain: DMPA shots at reduced prices, support to advertise clinics and DMPA training without any membership fees. Non-DIMPA clinics provide DMPA but do not enjoy the benefits of DIMPA membership.

Discontinuation rates at DIMPA and non-DIMPA clinics are high. So far little research has been done from the DMPA clients point of view regarding discontinuation rates and the factors affecting discontinuation. The proposed study of DIMPA and non-DIMPA clinics will have two components: 1) A phase I assessment to determine if a longitudinal study is feasible, and 2) A longitudinal study of both new and returning clients over one DIMPA injection cycle of contraceptive protection (3-4 months) to examine discontinuation rates reasons for discontinuation. This study is being co-funded by PSP-One (salaries) and FHI's CRTU Program (study costs).

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Activities, Accomplishments, Problems through December 31, 2005

- During October-November 2005, the technical monitor, R. Potdar, reviewed the PSP-One India's activities in promoting the uptake of DMPA via the DIMPA network in the three cities of Agra, Kanpur and Varanasi in India, and discussed with PSP-One India staff programmatic needs that required research. Survey instruments for the study were also developed.
- In December 2005, Potdar visited PSP-One India and met with their staff in Delhi to discuss the study design in detail, including topics to be covered in the client and provider questionnaires and possible strategies to recruit the sample of 1500 DMPA clients into the study. She also met with USAID contact persons in Delhi for their inputs into the study design.
- Potdar visited DMPA provider clinics in Agra and Kanpur and interviewed research agencies in Delhi that had bid to do the study. Their cost estimates were reviewed with PSP-One staff. The FHI/India Office and the relevant USAID/India contact persons were updated on the project.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- ACNeilsen, based in Dehli, was selected as the agency to conduct the fieldwork.
- Karen Katz replaced Potdar as technical monitor.
- Given the uncertainty of the numbers of clinics offering DMPA and the numbers of clients, it was decided to conduct a feasibility assessment (Phase 1) before designing the discontinuation study. The Phase I protocol was developed and approved during the first quarter of 2006.
- Exemption from PHSC review was received in May.
- A contract was negotiated and signed with ACNeilsen to conduct Phase I.
- Phase I data collection began in June 2006.

Funding Source(s):	Abt Associates/Collab. Agency; USAID - US Agency for International Development/Core	**FCO Approved: 12031**	Oct 2005
		114110	Nov 2005
Total Approved Budget: 12031	$ 69,493	**Projected End Date:**	Jan 2007
114110	N/A		

Nicaragua: Improving Continuation Rates for Injectable Contraceptives (FCO 114113)

Technical Monitor: DChin-Quee

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated

Objective(s): To collect information from users of all methods in order to develop interventions that will improve their continuation rates.
Note: After meeting with the Minister of Health in May 2006, FHI was asked to broaden the scope of the study to include all family planning methods in the investigation, not just injectables. The government felt that this was more in line with its needs, especially since USAID will cease the donation of family planning methods to Nicaragua in 2008.

Description: As part of a collaborative team composed of Johns Hopkins University and the Georgetown Institute for Reproductive Health, FHI's study on the "Evaluation of the Decision Making Tool for Family Planning Providers" revealed that use of the tool did not improve continuation rates for contraceptive users. The Nicaraguan Ministry of Health (MINSA) is particularly interested in increasing the continuation rates of all method users.
As a follow-up to the decision making tool study, FHI will design a study using Ministry of Health service statistics on method use and discontinuation, to inform interventions that will improve continuation rates of all family planning methods.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The Technical Monitor met with staff at the Ministry of Health in May 2006 to propose a study geared towards the improvement of continuation rates of family planning methods provided by the Ministry of Health. The Minister requested that FHI use its service statistics on method use and discontinuation to guide study design and objectives. The Minister also recommended meeting with the Commission on Sexual and Reproductive Health to get input that would ensure that the study meets the needs of the country.
- The Mission requested that Chin-Quee submit a two-to-three page concept paper to the Ministry, copying the Mission, before input from the Commission is sought. In May 2006, Chin-Quee received service statistics from the Ministry on use of methods. Information on the discontinuation of methods was not received as of June 2006. Consequently, development of the concept paper was put on hold.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Apr 2006
Total Approved Budget:	$ 234,666	**Projected End Date:**	Apr 2009

USA: Contraceptive Discontinuation: Setting the CRTU Research Agenda (FCO 113102)

Technical Monitor: EMcGinn

Status: Complete
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Strategies to enhance correct use and reduce discontinuation of hormonal methods developed and evaluated

Objective(s): To focus discussion on the topic of hormonal contraceptive discontinuation and help partners develop a consensus about research and research-to-practice priorities to improve continuation.

Description: Worldwide, over 100 million women use hormonal contraception, and this use is increasing. However, hormonal contraceptive prevalence may be a misleading measure of the success of family planning programs. Research suggests that at least 30 - 40 percent of women in many developing countries discontinue hormonal methods during the first year of use. Greater understanding and sharing of successful interventions to reduce discontinuation is needed to develop programmatic best practices. This subproject funded: a synthesis document on the topic of hormonal methods discontinuation, a CA workshop on the topic, dissemination of the proceedings and some CRTU development of concept proposals on the topic for FY 06-07.

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Activities, Accomplishments, Problems through December 31, 2005

- A synthesis document was prepared about hormonal method discontinuation as a background paper for participants of the workshop.
- A workshop was held in Washington, DC (November 29-30, 2005). It brought together approximately 50 representatives from 15 reproductive health research, training, and service delivery organizations, as well as USAID. Two participants were from the field – Gloria Asare from the Ghana Health Service and Bharat Ban from EngenderHealth/Nepal. Participants discussed key issues surrounding contraceptive continuation and identified knowledge gaps.
- Based on the discussions at the meeting, four concept proposals were developed for submission to the research priority setting process for the CRTU 2006-07 workplan. These were:
- "Improving Contraceptive Continuation: In-Depth Research to Identify More Promising Interventions" (submitted by BASS/Williamson).
- "Assessing and improving service delivery performance of community-based distribution of DMPA in Uganda" (submitted by HSR/Baumgartner; proposed collaboration with Save the Children as a follow-on to the CBD/DMPA Stanback subproject).
- "Development and evaluation of a campaign to increase continuation of hormonal contraceptive methods" (submitted by BASS/Burke/Geary).
- "Is lateness an issue for pill users in private sector pharmacies and public sector clinics?" (submitted by HSR/Chin-Quee).
- Two of the four concept proposals (Baumgartner/Burke) were approved for the FY 06-07 workplan.
- A report on the meeting proceedings was finalized and disseminated to meeting participants.
- Information Programs worked with the INFO Project to repackage information produced in the background paper and from the meeting, by writing short summaries of key points for providers, program managers, and trainings for a new digest series called Focus On.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Meeting proceedings were finalized and disseminated to meeting participants.

Findings and Outcomes:

- A final report of the meeting was developed and is available from Research to Practice staff.
- Several recommendations emerged, of which FHI felt four research questions could be addressed under the CRTU and subsequently submitted concept proposals for consideration. Two were funded for FY 06-07 and results should be available in 2008. There were no significant existing best practices or under used research findings on contraceptive continuation for which Research to Practice staff will undertake targeted utilization activities. Some information from the meeting background paper and final report will be synthesized in short summaries to appear in INFO's new digest series "Focus On."

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 124,550	**Projected End Date:**	Jun 2006

Worldwide: Pregnancy Provider Checklist & Reference Guide 2005 Update & Implementation (FCO 113107)

Technical Monitor: CLasway

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Other strategies and tools to enhance timely and convenient delivery of hormonal methods to women developed and evaluated
Strategies to enhance uptake of hormonal methods developed and evaluated

Objective(s): 1) To update the FHI Pregnancy Checklist in accordance with WHO's 2004 Medical Eligibility Criteria; 2) to revise pregnancy checklist reference materials and to produce and disseminate 2,000 reference guides and 9,000 pregnancy checklists; and 3) to promote the pregnancy checklist to CAs and PVOs, and provide technical assistance for its implementation and use in at least three in-country programs, in an effort to reduce medical barriers and increase access to FP.

Description: In many countries, 25 to 50 percent of women are denied a contraceptive method on their first visit to a family planning clinic because they are not menstruating at the time. The FHI checklist "How to be reasonably sure a client is not pregnant" provides an easy-to-use screening tool for various levels of health care providers, including physicians in resource-poor settings, pharmacists, or staff stationed at health posts. FHI research in Kenya and Guatemala demonstrated that the pregnancy checklist virtually eradicated the practice of turning away non-menstruating clients. The pregnancy checklist was developed based on WHO Medical Eligibility Criteria and under the CTR, it was both passively and actively disseminated through mailing lists, Network, conferences/workshops, and focused efforts under Research to Practice. It is a simple, low-cost job aid, easily implemented and replicable by in-country program managers with little or no assistance from FHI. FHI believes further outreach to CAs would encourage greater use in USAID-funded programs. Under the CRTU, FHI will work to promote the checklist to pharmacies,

VCT clinics, and other non-traditional family planning outlets, to increase access, improve referral mechanisms, and ultimately impact public health.

This subproject will provide support for technical review and update, printing, and dissemination of the Pregnancy Checklist, as well as the development of appropriate background materials in the form of a reference guide to facilitate implementation by programs. A pregnancy checklist promotion strategy will also be developed, outlining focused dissemination and outreach efforts, including global and enhanced focus-country components. It will include a systematic approach for documenting dissemination, follow-up, and (where possible) use of the checklist over a three-year period.

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Activities, Accomplishments, Problems through December 31, 2005

- By mid-October 2005, the FHI Pregnancy Checklist was updated in accordance with the 2004 WHO medical eligibility criteria.
- As of December 2005, a draft dissemination plan was developed in collaboration with the FITS Information Programs unit. This dissemination plan features initial and targeted distribution through traditional and non-traditional communication vehicles to global, focus, and non-focus country audiences.
- The pregnancy checklist has been promoted to Save the Children and ADRA through its inclusion in the menu of practices that were disseminated to these MoU partners in November 2005. In addition, the checklist is now part of the USAID Best Practices package (FCO 113115).
- Outreach to Ministries of Health in Kenya and Uganda, as well as other local stakeholders, to endorse the pregnancy checklist as a job aid were conducted between October and December 2005. In early December, a sub-committee of the Kenyan Family Planning Working Group reviewed the comprehensibility and acceptability of the checklist. The purpose of this review was to solicit feedback and facilitate endorsement of the pregnancy checklist by the MoH, as well as to seek permission to include a government MoH logo on the checklist. It is hoped that this co-branding process will promote local ownership of the checklist and thus increased uptake by providers.
- USAID/INFO developed a Technical Brief on Checklists; FHI provided review and supplied updated graphics.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- As of June 2006, a new version of the Pregnancy Checklist was developed and available in four languages: English, Spanish, French, and Kiswahili.
- In April 2006, electronic versions of the checklists were posted in 12 RH/FP list serves/online databases/newsletters, e-mailed to 4,439 persons present in the Online Rolodex, and five external non-FHI Web sites linked to the FHI Web site for this checklist. Furthermore, the checklist was sent to HPN officers in 53 missions worldwide.
- As of June 2006, a total of 12,000 laminated Pregnancy Checklists were printed in English, Spanish, and French languages. Of these, 32% have been distributed in response to requests from Madagascar, South Africa, Dominican Republic, Tanzania, and Romania.
- In-country dissemination plans for Kenya and Uganda to reach district level health providers, managers, and trainers have also been developed.
- The checklist was featured at the Global Health Conference (May 06), at the Program Design, Monitoring and Evaluation (PDME) Workshop in Dar, Tanzania (Feb 06), and has been included in the new JHUCCP Global Handbook for Family Planning (April 06), and a Counseling handbook in Zambia (through the WHO/UNFPA Strategic Partnership Programme).

Findings and Outcomes:

- The pregnancy checklist has been endorsed and co-branded with the Ministries of Health in Uganda and Kenya.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 125,000	**Projected End Date:**	Jun 2008

The availability and quality of health services directly affect the delivery of all contraceptive health technologies. Access to methods and services is often restricted by medical guidelines, availability of quality products, and economic constraints. Over the past decade, attention has been focused on integration of services to improve access, particularly the integration of STI and HIV services into family planning programs.

FHI CRTU Proposal, September 30, 2004, p.34 HIV and Contraceptive Methods

HIV/AIDS and CONTRACEPTIVE METHODS

FHI/NC subprojects fully or partially funded by USAID's CTR Agreement:

Ghana:	Rapid Assessment of Family Planning and Integration (FCO 3443 previously 3300)
South Africa:	PEPFAR: South Africa PMTCT Technical Assistance (FCO 3449)
Worldwide:	Contraception for HIV-infected patients, including those on ARV Therapy (FCO 3450)
Africa Regional:	Hormonal Contraception and HIV Research: Dissemination through Africa Regional and In-Country Meetings (FCO 3703)
USA:	Human Beta Defensins and HIV-1 Transmission (FCO 2708)
Kenya:	Evaluation of the Uptake of a Take-home Infant Dose of Nevirapine (FCO 9518)

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Brazil:	Pharmacokinetic Interactions between DMPA and ARV (FCO 112108 and previously 2289)
South Africa:	Developing and Testing Interventions to Serve the Family Planning Needs of PMTCT Clients in South Africa (FCO 114103)
South Africa:	Enhancing PMTCT Performance (FCO 153104)
South Africa:	Strengthening Linkages between FP, HBC and ARV Services (FCO 153105)
Kenya:	Improving Use of Family Planning in VCT (FCO 114104/153103)
Ghana:	Evaluation of Integrating Family Planning into ART Services (FCO 124101/114105)
Nigeria:	Rapid Programmatic Assessment for FP/VCT Integration (FCO 113105)
Worldwide:	Providing Global Leadership to Family Planning and HIV Integration Efforts (FCO 113104/123100)
Worldwide:	Tool Kit to Increase Access to Appropriate and Effective Contraception for Clients with HIV (FCO 113106)

Africa Regional:	Assessing Provision of Family Planning and Reproductive Health Services in Commercial Sector HIV/AIDS Programs (FCO 124102)
Worldwide:	Follow-Up: Sharing Information on HIV and Hormonal Contraception with Global Audiences (FCO 113119)
Kenya:	Kenya Information Management: Hormonals & HIV (FCO 143102)
Kenya:	Examining the Family Planning Needs of Women Traditionally Targeted for HIV/STI Services (FCO 124100)
Kenya:	Risk of HIV and Feasibility Research Among House Girls in Nairobi (FCO 154100)

Ghana: Rapid Assessment of Family Planning and Integration (FCO 3443 and previously 3300)

Technical Monitor: RWilcher
Collaborating Agency(s): Ghana Health Service
Status: Complete
Group: FITS

Objective(s): To gather information about VCT and family planning service provision in Ghana in order to inform the development of strategies for strengthening linkages between family planning and VCT services.

Description: This subproject was conducted in response to a specific request from the Reproductive and Child Health Unit of the Ghana Health Service (GHS). Little is known about the demand for and provision of family planning services in VCT settings, and what obstacles exist to effectively integrate family planning into VCT programs. As well, relatively little is known about the current demand for and provision of VCT services in family planning settings, and the obstacles that may exist for integrating VCT services into family planning programs. This rapid assessment was conducted in order to identify opportunities for and challenges to integrating family planning and VCT services, and to define programmatic options for strengthening the integration of these two services. The assessment consisted of a desk review of relevant epidemiological, programmatic, and policy documents and in-depth interviews with key informants, including family planning and VCT service providers, program managers, clients, and policymakers. FHI anticipated that the GHS and USAID/Ghana would use the findings from the assessment to inform the development and implementation of strategies for strengthening linkages between family planning and VCT services in order to better meet both the HIV and family planning needs of clients.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI secured PHSC approval to implement the assessment. The protocol was exempt from full review.
- Three local consultants were recruited and hired in May 2004.
- A desk review of relevant epidemiological, programmatic, and policy documents was carried out in May 2004. A draft of the key findings was completed in early June 2004.
- Approval to implement was received from USAID in June 2004 for FCO 3443 and August 2004 for FCO 3300.
- Interview guides for VCT clients, providers, program managers, and policymakers were created and reviewed by FHI staff and GHS staff.
- In June 2004, the FHI technical monitor traveled to Accra, Ghana. During this trip, the TM held preparatory meetings with the team members to review and discuss the assessment methodology, the key informant interview guides, the fieldwork itinerary, and general responsibilities and expectations. The technical monitor also visited several family planning and VCT sites selected for the fieldwork and co-facilitated interviews with other team members.
- All fieldwork was completed in July 2004, and summaries of the interviews with nearly 100 key informants were submitted by the field team to FHI.
- FHI staff analyzed and synthesized all interview data.
- A final report that compiled the desk review findings as well as the interview findings was drafted. The draft report was reviewed by the field team and other partners in the field.
- The final report, entitled “Integrating Family Planning and Voluntary Counseling and Testing Services in Ghana: A Rapid Programmatic Assessment,” was finalized, printed, and disseminated to the appropriate stakeholders in October 2004 (M# 2004-31).

- In February 2005, FHI disseminated the assessment findings at Advance Africa's regional conference on repositioning family planning.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The remaining funds were used to complete the end of project (CTR) report.

Findings and Outcomes:

- Overall the majority of key informants expressed support for integrating family planning and VCT services, explaining that integration offers an opportunity to make the best use of available facilities, logistics, and personnel to provide comprehensive, convenient reproductive health care. The desk review also revealed that most of the existing policies and guidelines for both HIV/AIDS and family planning in Ghana support linkages between the two programs. The assessment revealed many existing factors that facilitate the integration of family planning and VCT services in Ghana. These factors related to the general acceptability of integration. However, hindrances were identified in the areas of human resource capacity, facilities and logistics, and quality of care. In addition, factors related to stigma and gender dynamics were described as potential challenges to integrating family planning and VCT services.
- The assessment suggested that different levels of integration may be warranted at different facilities depending upon facility resources, logistics, and personnel. Therefore, the following were among the key recommendations to emerge from the assessment: guidelines that outline different levels of integrated service delivery should be developed; a facility assessment tool should be developed to help program managers determine the most feasible and appropriate level and direction of integration for their facilities; trainings should be offered to update providers' knowledge and skills on integrated service delivery, although the content of these trainings should be tailored depending on the level of integration that is feasible; and providers should be sensitized to conceptualize family planning and VCT as holistic, inter-related services, not as separate, distinct services.
- More details are available in the final report for this subproject, "Integrating Family Planning and Voluntary Counseling and Testing Services in Ghana: A Rapid Programmatic Assessment" (M# 2004-31).

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/Field Support		**FCO Approved:**	**3443**	Apr 2004
					3300	Jun 2004
Total Approved Budget:	**3443**	$	37,181	**Projected End Date:**		Jun 2006
	3300	$	29,360			
		$	66,541			

South Africa: PEPFAR: South Africa PMTCT Technical Assistance (FCO 3449)

Technical Monitor: WCastro

Status: Ongoing
Group: FITS

Objective(s): To provide technical assistance to 20 PMTCT sites in two provinces to establish the minimum package of services, including family planning counseling and referral.

Description: Currently FHI, in partnership with the South Africa National Department of Health (NDOH), is undertaking an investigation to produce information on the factors contributing to successful PMTCT services. During the initiation of the PMTCT investigation, it was clear that a number of NDOH PMTCT sites could be aided by technical support to build their capacity to offer the minimum of PMTCT services. The minimum package of PMTCT services includes: 1) counseling and testing for pregnant women; 2) ARV prophylaxis to the mother and newborn to prevent MTCT; 3) counseling and support for safe infant feeding practices; and 4) family planning counseling and referral.
FHI, through local consultants and assistance from the FHI/South Africa office, has conducted the following technical assistance (TA) activities: conduct rapid assessments of 20 PMTCT sites; provide TA to 20 PMTCT sites in two provinces in South Africa, focusing on reducing the barriers to voluntary counseling and testing (VCT) uptake and completion and including family planning counseling and referral; connect sites that need improvement with higher performing sites through organized study tours, time permitting; and document the processes and necessary steps to strengthen services. Areas of TA also included, but were not limited to: working with clinics to increase the number of clients accepting VCT and returning for results; strengthening pre/post-test counseling skills; incorporating family planning information into post-test counseling; and overall troubleshooting to improve VCT services. Training assistance and job aids were provided as needed.
The subproject is contributing to the PEPFAR goal of reducing mother-to-child transmission in severely affected areas in five years and aim to increase PMTCT uptake.
Note: This activity is being funded through the President's Emergency Plan for AIDS Relief (PEPFAR). It was also included in the CTR No-Cost Extension request submitted to USAID.

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Activities, Accomplishments, Problems through December 31, 2005

- Preliminary approval to develop this subproject was obtained on September 27, 2004. Approval to implement the subproject was obtained on November 23, 2004.
- In November 2004, two consultants based in South Africa were hired to identify sites, conduct assessments, and provide technical assistance. A workplan and timeline was developed.
- The provinces of Mpumalanga and Limpopo were selected based on PMTCT and VCT indicators. After initial delays in obtaining provincial approval in Mpumalanga Province, FHI initiated contact with Northern Cape Province. Agreement to move forward in Northern Cape was reached in January 2005.
- In January 2005, the FHI team in South Africa began site identification and conducted rapid assessments of basic PMTCT needs at 20 sites in Limpopo and Northern Cape Provinces, focusing on strengthening the VCT component of PMTCT service delivery and family planning counseling and referral.
- FHI provided technical assistance in reducing the barriers to VCT uptake and completion and increasing family planning counseling and referral in 20 selected sites.
- FHI offered technical assistance in counseling skills building, management, quality of care, logistics, infrastructure improvement, resource maximization, health information systems, and monitoring and evaluation.

- On June 30 and July 1, 2005, FHI held debriefing meetings with the two Provincial Departments of Health to provide them with a final report of the technical assistance provided.
- The funds to undertake this subproject were delayed, received in mid-to-late September 2004. This delay could have been an obstacle to having sufficient time to implement the activities and make significant progress towards planned objectives and targets. However, the project team took steps to deal with this challenge, including refining the scope of work to focus the provision of technical assistance in reducing barriers to VCT uptake and completion and including family planning counseling and referral.
- FHI completed final reporting requirements on the COP 04 activities for PEPFAR at the end of July 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Using no-cost extension funds, FHI staff and a consultant adapted a PMTCT refresher curriculum to build in lessons learned from this subproject as well as other FHI experience in PMTCT and FP/HIV integration in South Africa (FCOs 9402 and 3447).
- Staff collaborated with DOH in Limpopo and Northern Cape to plan for follow-on activities under FCO 153104. Plans for working in Northern Cape were finalized. FHI was unable to establish plans to work in Limpopo Province with the new staff in the Department of Health.
- All activities under this subproject were completed by June 30, 2006. This subproject and FCO were closed August 31, 2006.

Findings and Outcomes:

- The following policy and programmatic recommendations were made at the two provincial debriefings:
- In Limpopo Province, it was suggested that FHI assist the province to develop their own PMTCT protocol in the next phase of technical assistance. It was further suggested that the protocol be developed in collaboration with the Northern Cape, as they also need a local provincial protocol.
- Both Limpopo and Northern Cape Province have requested additional support in the provision of supervision skills training for supervisors, lay counselors, and professional nurses.
- There was an overwhelming consensus from both Limpopo Province and Northern Cape that the family planning component of PMTCT within the provinces needs to be strengthened and the province would like FHI to continue with the FP TA as a component of the complete package of PMTCT services that it provided thus far.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	Sep 2004
Total Approved Budget:	$ 200,000	**Projected End Date:**	Aug 2006

Worldwide: Contraception for HIV-infected patients, including those on ARV Therapy (FCO 3450)

Technical Monitor: MStalker
Collaborating Agency(s): EngenderHealth (Acquire Project)
Status: Ongoing
Group: FITS

Objective(s): To develop a new curriculum/training module to complement IMPACT's HIV/AIDS Treatment and Care Guide. This module will address the provision of contraception for HIV-infected women, including women on ARV therapy.

Description: This subproject will: develop a training module and support materials for counseling HIV-infected women, including those on ARVs, about their FP options; test and validate training content and learning methodologies, including the training-of-trainer (TOT) component; produce training materials in hard copy and electronic formats; and plan for dissemination of the training materials.
This activity was included in a No-Cost Extension request to USAID. As a result, activities are continuing through August 2006.

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Activities, Accomplishments, Problems through December 31, 2005

- USAID approved the subproject in December 2004.
- Ongoing conversations with EngenderHealth have been held to clarify roles and responsibilities. EngenderHealth was also involved in developing the content outline and serving on the expert review panel.
- A literature search was conducted.
- FHI vetted the draft module with content experts to finalize a draft for pre-testing in East Africa.
- Staff from NC and Nairobi conducted a field test with family planning and HIV providers from Kenya, Tanzania, Uganda and South Africa.
- The content and the format were finalized and submitted to USAID for final review and approval. USAID approved the module on June 29, 2005.
- A no-cost extension was granted to continue activities through August 2006.
- A CD-ROM version of the module, Contraception for Women and Couples with HIV, has been produced and 1,000 distributed to FHI's Nairobi office for dissemination to REDSO-funded partner organizations in East/Southern Africa.
- Four hundred copies were shipped to FHI's Arlington office for dissemination to HIV/AIDS service delivery programs.
- The module was presented at the Reproductive Health Research Unit's Priorities Conference in October 2005.
- The module has been adapted for training needs in South Africa through Emergency Plan programming.
- The module has served to frame a more comprehensive toolkit on integrating FP and HIV services (see FCO 113106).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The module was disseminated at The Global Consultation on the Rights of People Living with HIV/AIDS to Sexual and Reproductive Health in Addis Ababa in March 2006.
- The module has been posted to the SynergyAIDS.com site in March 2006.
- Training for REDSO partners in tailoring the content to FP and HIV/AIDS audiences was conducted.
- The FCO was closed on August 31, 2006.

Findings and Outcomes:

- The module served as a foundational resource, e.g., it has been adapted, to train providers in South Africa and Zimbabwe to integrate family planning into HIV services.
- EngenderHealth has also requested copies of the module for its programs in Ghana and Uganda.
- Due to increased demand, 2,000 additional copies of the module have been produced.
- The module has informed program/resource development efforts in numerous technical proposals to integrated family planning into HIV services.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Dec 2004
Total Approved Budget:	$ 150,000	**Projected End Date:**	Aug 2006

Africa Regional: Hormonal Contraception and HIV Research: Dissemination through Africa Regional and In-Country Meetings (FCO 3703)

Technical Monitor: KBest
Collaborating Agency(s): World Health Organization (WHO); International Planned Parenthood Federation (IPPF); Reproductive Health Research Unit, University of Witwatersrand

Status: Complete
Group: FITS

Objective(s): To promote evidence-based discussion and decision-making regarding hormonal contraceptive use, considering its possible relationship with HIV acquisition. The dissemination campaign aims to bring together researchers, policymakers, program managers, and women's advocates working in the HIV and reproductive health fields to learn about the relevant scientific data and discuss the possible programmatic and policy implications. It also will serve as an opportunity to highlight the importance of family planning in the HIV/AIDS era.

Description: Data from a soon-to-be published FHI-led study, funded by NICHD, will help clarify the possible association between hormonal contraceptive use and HIV acquisition. Disseminating his evidence-based information to ensure that appropriate family planning counseling messages are conveyed has been deemed a priority. A dissemination meeting for the Africa Region was held in September 2005 in Nairobi, Kenya. Approximately 100 participants, including MOH representatives, HIV/AIDS NGO representatives, women's advocates, researchers, and donors, attended from 17 different sub-Saharan African countries. Because the FHI-led study was not published as of June 30, 2006, activities to disseminate confidential findings could not proceed. For example, in-country dissemination meetings planned for Uganda, Zimbabwe, and Thailand were put on hold. However, background materials for eventual, widespread dissemination were prepared and overview materials for meeting participants were written, translated, printed and shipped.

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Activities, Accomplishments, Problems through December 31, 2005

- A meeting for the Africa Region to disseminate information about hormonal contraceptive use and HIV was held in September of 2005 in Nairobi, Kenya. Approximately 100 participants,

including MOH representatives, HIV/AIDS NGO representatives, women's advocates, researchers, and donors, attended from 17 different sub-Saharan African countries.
- A meeting proceedings, written in English (under FCO #113119), was printed and sent to English-speaking meeting participants. Under FCO #3703, the 36-page document was subsequently translated into French, printed, and distributed to French-speaking meeting participants.
- A PowerPoint overview of the meeting proceedings was written in English, reviewed, and translated into French.
- Background materials about the relationship between hormonal contraceptive use and HIV were translated into French. These include Network, a Q&A, country-specific fact sheets, and a Global Technical Brief.
- A VCT job aid was developed in English and translated into French.
- Documents were prepared to support media (print and radio) dissemination of results of the Exemplars Study (a sub-study of the HC-HIV study that illustrated how men/women in primary relationships in Uganda can use condoms consistently).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006
- The remaining funds were included in the no cost extension for 1) dissemination of Examplars study on consistent condom use in Uganda; 2) development of HC/HIV CD-ROMs, which contained various documents related to HC/HIV including Network, the HC/HIV Africa Regional Meeting proceedings, FHI Q&A on HC/HIV, a Global Technical Brief on HIV acquisition, transmission and disease progression, a VCT provider job aid, country-specific fact sheets for Uganda, Zimbabwe, Thailand and a PowerPoint Presentation targeted at service providers; and 3) translating, printing, & shipping meeting proceedings.
- The FCO was closed on August 31, 2006.

Findings and Outcomes:
- All HC/HIV-related documents and tools developed under this FCO will be placed on an CD-ROM and distributed, as well as being posted electronically to the FHI Web site, when results of the FHI-led, NICHD-funded study are published.
- Results of the Exemplars study were disseminated via a radio talk show in Luganda, the most widely spoken language in Uganda next to English, and a similar talk show is planned. FHI-produced articles about the findings have been submitted to Ugandan newspapers.

Funding Source(s):	USAID - US Agency for International Development/OYB	**FCO Approved:**	Jun 2005
Total Approved Budget:	$ 100,000	**Projected End Date:**	Aug 2006

USA: Human Beta Defensins and HIV-1 Transmission (FCO 2708)

Technical Monitor: CMorrison

Status: Complete
Group: CRD

Objective(s): To compare the expression of human beta-defensins (hBDs) from the genital tract of HIV-infected women and HIV-seronegative women at moderate to high risk of HIV-1 infection in Uganda and Zimbabwe in order to evaluate a potential correlation between expression of hBDs in the cervix/vagina and transmission of HIV-1.

The secondary objective of this subproject is to analyze the potential effect of hormonal contraception and pregnancy in the expression of hBDs in the genital tract of women from the Ugandan and Zimbabwean cohort and how this may correlate to protective immunity against HIV at the mucosal level.

Description: For the primary objective, both cross-sectional and longitudinal studies will be performed using samples from the HC-HIV study (FCO 502). In the HC-HIV study, 4500 women were tested for HIV-1 seroconversion every three months and samples were taken. Plasma swabs of endocervical or vaginal mucosa have been stored in a repository. In addition, demographic and sexual behavior information and testing for pregnancy, sexually transmitted diseases and cervical ectopy have been obtained longitudinally. Vaginal and cervical swabs will be obtained from four groups of HIV-infected women based on CD4+ T-cell counts (i.e.,< 50; 50-199; 200-500; and >500 cells/ l), with no restrictions in their HIV RNA plasma level. Ten HIV-infected women will be included in each group for a total of 40 samples. Cervical and vaginal swabs from 40 HIV-seronegative women at moderate to high risk for HIV-1 infection will also be evaluated.

For the secondary objective, samples will be obtained from three different contraceptive groups: (i) non-users, (ii) COC users, and (iii) DMPA users. These three groups will be further subdivided into HIV-negative and HIV-positive women. A total of 20 individuals per group will be analyzed.

This study will contribute to a better understanding of the biological and/or clinical significance of the association of hBDs in the genital tract of HIV-infected women with HIV-1 transmission, perhaps making feasible the use of these natural peptides or hBD-derivatives to prevent HIV-1 infection.

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Activities, Accomplishments, Problems through December 31, 2005

- The Approval to Implement letter and subagreement for Cleveland Clinic Foundation was approved by USAID in February 2004.
- Analysis of cervical/vaginal swabs collected from women in Uganda began in mid-2004.
- Quantification of hBD expression and proviral HIV-1 DNA began in late 2004.
- HIV-1 sequencing and co-receptor usage analyses began in late 2004.
- This activity was included in a No-Cost Extension (NCE) granted by USAID for this NIH Inter-agency Agreement.
- A total of 137 HIV-positive cervical specimens from Ugandan women were tested. These included 40 at 6 months pre-seroconversion, 40 at 3 months pre-seroconversion, 45 at seroconversion and 12 at 6 months post-seroconversion.
- The study completion date was extended ten months by the NCE and NIH supplied an additional $35,000 to this subproject.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Cervical specimens from 50 HIV-negative Ugandan women at high-risk for HIV-infection at two separate visits were tested.
- The subagreement for cost and reimbursement purposes expired on March 31, 2006.
- A decision was made not to collect or process Zimbabwe specimens for the analysis due to uncertainty regarding consent issues.
- A profile dataset including data on sociodemographics, hormonal contraceptive use, pregnancy and STI information along with hBD data was created.
- The FCO was closed on August 31, 2006.

Findings and Outcomes:

- No significant difference in expression of human beta-defensins between HIV-negative and HIV-positive Ugandan women was detected.
- hBD-2 copy numbers at seroconversion did not correlate with cervical HIV-1 viral load.
- Three different patterns of hBD-2 expression were observed: 1) expression of hBD-2 decreased after seroconversion (7/14); 2) hBD-2 increased after seroconversion (5/14); and 3) no significant change in hBD-2 expression occurred during visits (2/14).
- There is little difference in hBD-2 expression between the 6 and 3 month pre-seroconversion visits.
- The inflexion point in hBD-2 expression (major increase or decrease) appears to occur at seroconversion.

Funding Source(s):	USAID - US Agency for International Development/OYB	**FCO Approved:**	Sep 2003
Total Approved Budget:	$ 202,854	**Projected End Date:**	Aug 2006

Kenya: Evaluation of the Uptake of a Take-home Infant Dose of Nevirapine (FCO 9518)

Technical Monitor: HReynolds

Status: Complete
Group: HSR

Objective(s): To examine whether offering the infant dose of nevirapine to take home increases uptake.

Description: Assuming the infant dose is important to prevent MTCT, this study will examine whether offering the infant dose to take home increases uptake. This study is more descriptive in nature, although we propose to employ a non-randomized post-test only, control group design. Comparing the current standard of care (infants get their NVP dose at the facility within 72 hours) with the new strategy (to give the dose to the mothers to administer at home), the study seeks to measure the proportion of HIV+ pregnant women in antenatal care (ANC) who received the infant take home NVP dose and the proportion of women who give the infant dose.
To implement the study, we are working in sites supported by FHI, and providers systematically fill and distribute the infant dose to all women greater than or equal to 32 weeks gestation in a subset of facilities. We are collaborating with PATH on this project who has developed packaging material for the infant dose. Another subset of women in matched facilities will serve as the control group. We will follow up women in the training group at home to interview them about their experiences with the infant NVP dose. In the control group, we will also follow up HIV-

infected women who attend ANC at greater than or equal to 32 weeks to understand the factors that facilitated them to take their infant for the dose at the facility or not. We will compare the proportion of women whose infants received the NVP dose between the two groups. We will also be able to investigate the factors associated with NVP use or non-use. The major limitation of the study is we rely on women's reports. This activity was approved for spending and continue as a no-cost extension activity of the CTR through August 31, 2006.

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Activities, Accomplishments, Problems through December 31, 2005

- The protocol was prepared, reviewed, and approved by FHI's PHSC on November 11, 2005.
- Data collection instruments were finalized in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Kenyatta National Hospital's Ethical Review Committee approved the study in February 2006.
- The consultant was hired in February 2006.
- Research assistants were trained during March 2006.
- FHI staff traveled to study sites in April 2006 to train providers in infant nevirapine dose filling and distribution.
- Data collection and data entry started in March and is expected to end in July 2006.

Findings and Outcomes:

- Providers and clients expressed positive attitudes toward implementing and using the take home infant nevirapine dose, including the packaging designed by PATH. In general, however, providers felt that HIV-related stigma and fear about HIV status disclosure limited their ability to provide any nevirapine including the mother or infant's dose. Indeed, even among those clients who accepted to take home the infant's dose, knowledge of partner's HIV status and disclosure of the woman's status to her partner were rare. Some providers also mentioned that counseling time constraints and stockouts were limitations to provision.

- In terms of uptake of the infant's nevirapine dose, uptake was very high in both intervention and control group. Although uptake was slightly higher in the intervention group, especially among those women in the intervention group who delivered at home, it is not likely that statistical difference are found. High levels of institutional delivery and some control group clients getting a take home dose resulted in a higher level of uptake than anticipated. Place of delivery was not affected by the availability of the take home dose.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	$ 200,000	**Projected End Date:**	Aug 2006

Brazil: Pharmacokinetic Interactions between DMPA and ARV (FCO 112108 and previously 2289)

Technical Monitor: KNanda

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least two clinical studies of the safety and effectiveness of hormonal contraceptives and ART completed.

Objective(s): 1) To evaluate the effect of common ARV therapies (AZT/3TC + EFV) on the pharmacokinetics of DMPA; and 2) to evaluate the effects of ARV treatment on bleeding patterns with DMPA.

Description: Pharmacokinetic data suggest that some antiretroviral (ARV) agents may affect the metabolism of single dose oral contraceptive steroids, but it is not clear whether these interactions actually result in a loss of contraceptive efficacy. No such data are available regarding the pharmacokinetics of depot-medroxyprogesterone acetate (DMPA) and ARVs. This subproject will study the effects of selected ARV therapies on the pharmacokinetics of DMPA and on DMPA-related bleeding. Given the frequency of DMPA use for contraception among HIV-infected women, it is important to study potential drug interactions with ARV drugs, so that women being treated with ARVs can be properly advised about their options for preventing pregnancy.

This is a 12-week open-label, non-randomized, unblinded, prospective non-comparative pharmacokinetic study of reproductive-aged women on current antiretroviral (ARV) therapy. Fifteen reproductive age HIV-positive women who have been receiving a standard regimen of ARV treatment for at least one month and who are willing to take a single dose of DMPA will be enrolled in this study. Fifteen women will also be enrolled on DMPA alone. Each woman will be followed for 12 weeks.

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Activities, Accomplishments, Problems through December 31, 2005

- Preliminary approval to develop this subproject was obtained from USAID in July 2004.
- A study team was selected, a timeline was developed, and planning meetings were held.
- A site in Brazil capable of conducting the study in a relatively short time was identified.
- The PHSC approved the protocol in August 2004.
- The study team selected FIOCRUZ lab for bioequivalence testing in August 2004.
- A subagreement with the Center for the Research and Control of Maternal-Infant Diseases of Campinas (CEMICAMP) was approved in October 2004.
- FHI staff conducted a site initiation visit in October 2004.
- The local IRBs approved the study protocol in August 2004, September 2004, and December 2004. Delays in site IRB approvals led to a delay in study initiation.
- Data collection forms were completed in January 2005, and the study manual was finalized in February 2005.
- The site enrolled the first study participant in March 2005.
- In June 2005, FHI staff conducted an interim monitoring visit; study recruitment of 30 women was successfully completed in July 2005.
- Follow-up was completed in October 2005.
- Laboratory testing was conducted between November and December 2005.

- Problems regarding test results of some participants were discovered.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006
- Results were reviewed, discussed with laboratory personnel, and some retesting of samples was done.
- The close-out monitoring visit was completed in February 2006.
- Laboratory retesting was completed as required.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved:**	**2289**	Jun 2004
				112108	Jul 2005
Total Approved Budget:	**2289**	$ 283,823	**Projected End Date:**		Mar 2007
	112108	$ 295,812			
		$ 579,635			

South Africa: Developing and Testing Interventions to Serve the Family Planning Needs of PMTCT Clients in South Africa (FCO 114103)

Technical Monitor: THoke

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To explore with providers and clients the feasibility and acceptability of alternative strategies for linking FP services to PMTCT services; and 2) to measure how such linkages affect FP uptake among women who have completed PMTCT services.

Description: South Africa's National Department of Health has given priority to providing Prevention of Maternal to Child Transmission (PMTCT) services to prevent HIV infections. Even though South Africa's national service delivery guidelines advocate the provision of FP in the PMTCT package of care, few efforts have been made to integrate the two services.
To address this issue, FHI proposes a two-phase study. Phase I will consist of formative research. Interviews with PMTCT clients in 6 sites will assess the priority they place on preventing or delaying a future pregnancy and will explore their interest in receiving FP services under different service delivery configurations e.g. during antenatal care, post-partum visits, immunization and well baby check-ups. Providers and facility supervisors of each of these services will also be interviewed to assess their willingness to take on the added responsibility of providing FP services. Results of data collection will be shared with program managers, who will identify one or two integration interventions that appear to be the most feasible.
Phase II will consist of operations research to test the selected interventions. It is anticipated that for each intervention, five matched pairs of PMTCT sites will be identified to participate. At baseline, PMTCT clients consenting to be re-contacted will be interviewed to assess their current contraceptive use. For each of the five matched pairs of PMTCT sites, one site will be randomly assigned to receive the intervention and the other site will continue delivering PMTCT as usual.

After a 6-month follow-up period, another cross-section of PMTCT clients will be interviewed. Process data will also be collected to assess the extent to which the intervention was implemented as intended. Finally, the cost of implementing the intervention will be computed to inform decisions about scale-up.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The technical monitor met with University of Cape Town (UCT) investigators to discuss potential partnership and a general implementation strategy.
- In March 2006, the technical monitor and a UCT collaborator traveled to Free State to discuss provincial participation in the study.
- In May 2006, a protocol for the formative research was prepared and submitted for review by PHSC and the ethics committee at University of Cape Town. Approvals were granted contingent on minor changes recommended by both committees.
- Data collection instruments were drafted.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 358,000	**Projected End Date:**	Mar 2008

South Africa: Enhancing PMTCT Performance (FCO 153104)

Technical Monitor: WCastro

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs

Objective(s): 1) To provide technical assistance to 30 sites in South Africa to design, develop, and implement high quality, comprehensive and cost effective PMTCT programs, with an emphasis on strengthening family planning counseling and referral. 2) To expand upon lessons learned from previous FHI projects in PMTCT and FP/HIV integration (FCOs 3449, 9403, and 3447). 3) To assist the provincial departments of health with the development and finalization of provincial PMTCT protocols?
Note: Objective 3 was separated out from the general technical assistance as the DOH has directly asked FHI for this support.

Description: With funding from the President's Emergency Plan for AIDS Relief, FHI will use the information generated from FHI's previous investigation of high performing sites in South Africa (FCO 9403) to design, develop and implement high quality, comprehensive and cost-effective PMTCT programs in 30 PMTCT sites. Using core funds from the CRTU, FHI will continue to provide TA under the new subproject to a sub-set of the 20 sites that received TA under the South Africa Country Operational Plan (COP) 04 funding cycle (FCO 3449). These sites are located in Limpopo and Northern Cape provinces. FHI also will provide TA to additional PMTCT sites in these provinces for a total of 30 sites combined.

The TA provided under this funding cycle will build upon the lessons learned from the assessment by identifying the factors that contribute to the success of high performing PMTCT sites. These best practices will be adapted for and transferred to programs in the 30 selected sites.
Evidence from the assessment indicates that family planning is an underdeveloped or neglected component of most PMTCT packages. Hence, the TA will focus on strengthening the family planning counseling and referral component of PMTCT services. Approximately 10 providers per site (a total of 300 providers) will be trained to meet these goals. The information gathered from the performance improvement investigation will also be used to inform a review of national PMTCT program policies and guidelines and provincial protocols in South Africa.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI identified a consultant to revise the PMTCT refresher training to strengthen the focus on providing family planning counseling, services and referrals in the PMTCT program. The revised training incorporates materials and messages from: PMTCT refresher training developed by FHI/South Africa in 2005 (FCO 3449); FP Integration training developed by FHI/South Africa in 2005 (FCO 3447); the final report of the PMTCT evaluation conducted in 2005 (FCO 9403); and the Contraception for Women and Couples with HIV module developed by FHI and the ACQUIRE project.
- Training on the above-cited manual has been conducted in four districts of the Northern Cape province.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In January 2006, FHI's South Africa Project Director met with staff from the Department of Health, Northern Cape Province to select districts to participate in the PMTCT/FP refresher training program. At this time, it was decided that the Training of Trainers model would not work well for the province. A schedule of 6 trainings for auxiliary nurses and lay counselors was developed for selected districts in the province.
- In February 2006, the approval to implement was obtained.
- FHI conducted a rapid needs assessment in Northern Cape of 21 PMTCT sites in the selected districts in March 2006 in order to gather information about programmatic and training needs.
- In March 2006, FHI pilot tested the training curriculum with the Francis Baard training group.
- From March to June 2006 trainings were held for selected auxiliary nurses and lay counselors in the following districts: Northern Cape Province: there were 26 participants in Francis Baard/Kimberly, March 6-9; there were 18 participants in Galagadi, May 8-12; there were 22 participants in Pixley – Ka – Seme, June 5-9; and there were 22 participants in Namaqualand, June 19-23.
- Feedback from these trainings has been incorporated into further revisions and improvements in the manual to best meet the knowledge and skill level of the auxiliary nurses and lay counselors.
- At the end of June, the Northern Cape Provincial meeting to discuss the PMTCT protocol development was postponed by the DOH.
- Attempts to engage Limpopo Provincial DOH staff to collaborate on the TA project in their province initially stalled. FHI's Project Director has arranged to meet again with the Limpopo DOH in July to discuss how to move forward.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 175,000	**Projected End Date:**	Apr 2007

South Africa: Strengthening Linkages between FP, HBC and ARV Services (FCO 153105)

Technical Monitor: ECanoutas
Collaborating Agency(s): Right to Care; BroadReach
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To build communication and referral skills of HBC volunteers regarding pregnancy prevention as an effective PMTCT approach; 2) to build clinical counseling skills of family planning providers and ARV providers, regarding pregnancy prevention as an effective PMTCT approach and contraceptive methods that are safe for HIV-infected women and HIV-infected women on ARVs; 3) to build the skills of HBC volunteers to provide basic information about VCT, the availability of and access to ARV services, and to assist HBC clients to adhere to the treatment regimen; 4) to strengthen referral mechanisms between HBC programs and FP, VCT, and ARV services; and 5) to conduct a process evaluation of the subproject.

Description: Since 2003, FHI has supported the Project Support Association - South Africa (PSA-SA) HIV/AIDS home-based care (HBC) program to integrate FP into the basic package of services provided by volunteers in Mpumalanga province (FCO 3441). Access to family planning services is a key public health intervention particularly in the context of HIV. Simulation models suggest that HIV prevention goals can better be met when a combination of interventions are used, including access to contraception for HIV-infected women and those in PMTCT programs. It is anticipated that improved access to ARV services in South Africa will lead to the improved health status of many HIV-positive individuals, leading to a return of libido and sexual activity, and thus requiring careful decisions about contraception. Tighter linkages between care, VCT, ARV and contraceptive services will be needed so that women not only have the opportunity to improve their quality of life, but also make informed decisions about their fertility.

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Activities, Accomplishments, Problems through December 31, 2005

- Subproject funds were received in early October 2006.
- The FHI Project Director in South Africa and the FHI/NC Technical Monitor met soon thereafter with in-country partners, the USAID Activity Monitor, and South Africa Department of Health officials to shore up support and further develop the subproject scope of work and activity timeline.
- FHI, PSA-SA and SACC identified 30 HBC project sites in Mpumalanga and Kwazulu Natal Provinces.
- In collaboration with PSA-SA, the FHI Project Director interviewed candidates for the VCT position, with assistance from staff in the FHI Institute for HIV/AIDS (IHA).
- The FHI Medical Advisor revised the training module on contraception and HIV in preparation for training family planning providers and ARV providers (to be conducted separately).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The ATI letter was submitted to USAID in February 2006.

- FHI staff designed and finalized training materials and provider tools with subproject partners. The training module includes risk-reduction communication skills; how to communicate and refer for FP, VCT and ARV; and how to establish formal referral networks.
- With project partners, FHI staff hired and oversaw 4 project coordinators from PSA-SA and SACC. The TM and the SA Project Director met with the project coordinators in March to review project goals, draft detailed job descriptions, review reporting requirements, and discuss overall implementation plans.
- The Senior BCC officer traveled to SA to conduct training for 42 PSA-SA and SACC volunteers from 30 sites in Mpumalanga and KwaZulu Natal. The project coordinators led the training on communications, FP, VCT and ARV topics.
- The project coordinators provided training and TA to 419 HBC volunteers: to identify FP and VCT needs among clients, caregivers and their families; to refer clients to FP and VCT clinics; and to track referrals. In the March-May period, 107 referrals to FP and 81 referrals to VCT were completed.
- FHI's Medical Advisor conducted two trainings for 24 FP providers and 5 ARV providers on appropriate contraception for HIV-infected women of childbearing age and HIV-infected women on ARVs (using the FHI FP/ARV module).
- Through project coordinators, FHI trained 363 HBC volunteers to refer clients to ARV services, and to assist clients to begin using and monitoring adherence to ARV therapy (in collaboration with BroadReach and FHI IHA staff). In the March-May period, 111 referrals to ARV clinics were completed.
- The hiring of the VCT nurse through project partner Right to Care has been delayed. FHI and Right to Care are working out the details of the MOU. (This is being done in collaboration with FHI IHA staff).
- The TM completed the design of the M&E plan for the program. Information is being compiled and recorded through project partners.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 365,000	**Projected End Date:**	Sep 2006

Kenya: Improving Use of Family Planning in VCT (FCO 114104/153103)

Technical Monitor: HReynolds
Collaborating Agency(s): Ministry of Health, Kenya
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three scalable and appropriate models given the CPR, HIV prevalence, and available services for integrating family planning and HIV services designed, evaluated and introduced in up to five countries.

Objective(s): 1) To determine the effect of family planning provision in VCT on the uptake of contraceptive methods among VCT clients; 2) to develop and target messages to men in VCT programs and to assess whether these efforts strengthen family planning messages and services for men; and 3) to determine how to strengthen overall VCT providers' family planning messages and provision for both men and women.

Description: This subproject, which will be co-funded with CRTU core funds and funds from the President's Emergency Plan for AIDS Relief, will strengthen the provision of integrated FP/VCT services in a subset of VCT centers in Kenya and evaluate the effect of integrated services on contraceptive uptake. The development and implementation of an enhanced integration intervention will be funded by PEPFAR (FCO 153103). Core components of the intervention will include: holding provincial- and district-level sensitization meetings to orient managers and other health personnel to the integration effort; training all VCT providers in a subset of VCT centers who were not previously trained in FP/VCT integration; implementing targeted family planning messages to male VCT clients; and conducting support supervision for trained providers. CRTU core funds (FCO 114104) will be used to conduct research activities, including collecting formative data on appropriate family planning messages for male VCT clients, testing the effectiveness of the enhanced integration intervention, and collecting monitoring and evaluation data. The effectiveness of the intervention will be measured by assessing the proportion of VCT clients at risk for unintended pregnancy who begin using a method of contraception. We will rely on two groups, post-test only design, where we will collect data from a subset of clinics receiving strengthened integration activities and in a group of control clinics. Monitoring data will be collected from a VCT client card that has been modified to include family planning indicators. All activities under this subproject will be implemented in collaboration with the Kenya Ministry of Health.

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Activities, Accomplishments, Problems through December 31, 2005

- Meetings were held with representatives from the MOH in November 2005 to develop plans for the subproject. Agreement was reached on the sequence and timing of the subproject activities.
- FHI staff gave two presentations, one on the operations research results and one on the integration process (see reports for FCO 9390), at the annual meeting of the American Public Health Association meeting in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on February 2, 2006.

- Four one-day dissemination/ sensitization/ advocacy meetings were held with a total of 58 VCT counselors and 71 VCT supervisors and MOH managers representing seven provinces in March 2006.
- FHI called two FP-VCT subcommittee meetings, one in February 2006 and one in May 2006, to get buy-in from committee members on planned activities.
- Two trainings were held in Busia and Mombasa for 47 VCT providers in March 2006.
- A two-day meeting with members of the FP-VCT integration subcommittee was held in June 2006 to work towards finalizing the FP-VCT training manual.
- Margaret Gitau, NASCOP, presented the results of the integration process and OR results at the PEPFAR Annual Meeting in Durban, South Africa in June 2006.
- Reynolds began working with the project biostatistician to determine sample sizes needed for the operations research aspect of the subproject.

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	**153103**	Sep 2005
				114104	Sep 2005
Total Approved Budget:	**153103**	$ 52,900	**Projected End Date:**		Jun 2007
	114104	$ 362,217			
		$ 415,117			

Ghana: Evaluation of Integrating Family Planning into ART Services (FCO 124101/114105)

Technical Monitor: BJanowitz
Collaborating Agency(s): EngenderHealth; FHI/Institute for HIV/AIDS

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three strategies targeted to specific populations and implemented by HIV and/or FP providers developed, evaluated, and introduced into programs in five countries.

Objective(s): 1) To determine whether providers are implementing newly trained skills, i.e., assessing clients' fertility preferences and providing family planning services; 2) to determine the effect of the intervention on contraceptive acceptance among HIV+ women enrolled in antiretroviral treatment; and 3) to identify the fertility desires and intentions of HIV+ women who are enrolled in an ART program.

Description: Little is known about how the availability of ARV affects fertility desires of women and men living with HIV/AIDS. It has been hypothesized that as health status improves with ARV, some individuals may resume or increase sexual activity and wish to have children, while others may not want to become pregnant. Documenting changes in fertility intentions and monitoring pregnancy status over time among individuals receiving ARV can inform HIV programs about appropriate strategies for incorporating family planning into their services.

This work will be a joint undertaking among: FHI's IMPACT Program, which supports four ARV sites in Ghana; EngenderHealth's ACQUIRE Project, which has trained providers to offer FP counseling and services at two ARV sites; and FHI's CRTU Program, which will evaluate the intervention.
Relevant process and output indicators will be measured including: whether accurate and appropriate FP information is communicated by providers; contraceptive uptake; and referrals made. Data collection methods will include observation of client-provider interactions, and client exit interviews. To assess changes in contraceptive use, fertility intentions, and pregnancy status among clients, women will be interviewed before being seen by a provider, and again after the consultation has taken place.

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Activities, Accomplishments, Problems through December 31, 2005

- A consultant, Susan Adamchak, developed data collection instruments in the fall of 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained on February 20, 2006.
- Adamchak and Janowitz prepared the research proposal for expedited review by the PHSC; the protocol was approved in March 2006.
- The proposal and data collection instruments were also submitted to the Ghana Health Service IRB.
- Training of the data collection team took place in February-March 2006.
- Data collection began and will be completed in July.
- Lily Wang prepared the first phase of the data analysis plan.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 335,925	**Projected End Date:**	Sep 2007

Nigeria: Rapid Programmatic Assessment for FP/VCT Integration (FCO 113105)

Technical Monitor: WCastro/JWesson
Collaborating Agency(s): Ministry of Health, Nigeria
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs

Objective(s): To generate and document strategic information on potential facilitating factors and obstacles to integrate family planning and VCT services effectively in the Nigerian context.

Description: Nigeria meets the definition of a generalized HIV epidemic. Accordingly, USAID's technical guidance on FP/HIV integration recommends that all FP and HIV services should be integrated. Currently, as part of the GHAIN (Global HIV/AIDS Initiative Nigeria)

Program, FHI is working with the uniformed services in Nigeria, focusing on integrating FP/RH and HIV services. USAID/Nigeria is committed to integrating SO13 (FP/RH, Child Survival, and Basic Education) and SO14 (HIV/AIDS and TB) interventions for the general population as well.

This subproject supports a rapid programmatic assessment for FP/VCT integration as the first phase in a holistic approach to integrate FP and VCT services, which will directly contribute to USAID/Nigeria's integration goal. Sites selected for the assessment will represent the six geopolitical regions of Nigeria as well as the different tiers of the health care system. It is anticipated that approximately 20 VCT sites will be included in the assessment. As the key agency coordinating integration activities with the uniformed services, we are recognized by USAID/Nigeria and other implementing partners as the organization leading FP and HIV integration in Nigeria and have recently received additional funding from USAID/Nigeria to support integration.

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Activities, Accomplishments, Problems through December 31, 2005

- Initial contact was made with the Nigerian Ministry of Health to ascertain interest in and secure commitment to the rapid programmatic assessment. It was agreed by the MOH and FHI that, prior to implementation, wider support from partners for the rapid programmatic assessment needs to be secured at the January 2006 national stakeholders' meeting on RH and HIV integration.
- Additional funding was secured from FHI's Global HIV/AIDS Initiative Nigeria (GHAIN) to complement the activities by conducting the rapid programmatic assessment in selected FP clinics to explore FP clinics' preparedness to integrate VCT services.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- At the first meeting of the Nigeria Integration Technical Working Group (ITWG) in March 2006, the research subgroup agreed that the rapid programmatic assessment will help meet the objectives of the ITWG and will become part of the ITWG workplan.
- FHI staff drafted data collection forms, originally adapted from FHI's Ghana rapid programmatic assessment (FCO 3300 and 3443).
- In June 2006, FHI hosted a one-day assessment planning meeting at the GHAIN office (Abuja, Nigeria) for the ITWG research sub-group to review the data collection tools and begin planning for the field work.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 60,000	**Projected End Date:**	Jun 2007

Worldwide: Providing Global Leadership to Family Planning and HIV Integration Efforts (FCO 113104/123100)

Technical Monitor: RWilcher

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened
Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs

Objective(s): 1) To strengthen support for family planning as an HIV prevention intervention; 2) to promote dissemination and utilization of the latest scientific evidence and programming tools on FP/HIV integration and contraception for HIV-infected and at-risk women; 3) to establish partnerships and collaborations with other organizations working on HIV and contraception activities; and 4) to facilitate strategic placement of new HIV and contraception research and programs in the field.

Description: Since 2003, FHI has become increasingly involved not only in research and programs designed to increase contraceptive use in the context of the HIV/AIDS epidemic, but also in leadership efforts to garner support for such research and programming. By establishing and coordinating USAID's Family Planning and HIV/AIDS Integration Working Group, hosting key events at international HIV/AIDS and RH conferences, and facilitating country-level integration efforts, FHI has been at the forefront of efforts to expand access to and use of contraceptives by HIV-infected and at-risk women.
This subproject will support a number of activities that will allow FHI to build on the leadership role it has established in the arena of HIV and contraception and continue to advance research and programming.
First, FHI will continue to participate in and provide leadership to the Family Planning and HIV/AIDS Integration Working Group. Second, FHI will host satellite sessions on HIV and contraception-related topics at high-profile international HIV/AIDS and/or RH conferences. Third, FHI will maintain involvement in and operation of field-based working groups addressing HIV and contraception issues. Finally, FHI will leverage and work with its Research-to-Practice Network of Champions to foster local partnerships and collaborations on integration activities and identify field-based opportunities to apply emerging research findings.
All of these activities will contribute to: increased awareness of the importance of contraception as an HIV prevention intervention; improved dissemination and utilization of the latest scientific evidence on FP/HIV integration programming and contraception for HIV-infected and at-risk women; and the strategic placement of more integration research and programming in the field.

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Activities, Accomplishments, Problems through December 31, 2005

- At the 12th Priorities in Reproductive Health and HIV Conference in South Africa in October 2005, FHI's Principal Investigator of the NICHD-sponsored "Hormonal Contraception and Risk of HIV Acquisition Study" delivered a keynote address presenting the results of the study. Also at the Priorities Conference, FHI's Zimbabwe-based staff member presented the findings from a study assessing the feasibility and acceptability of FP/VCT and FP/PMTCT service integration in Zimbabwe. Both presentations were supported by this subproject.

- In October 2005, the technical monitor, R. Wilcher, and another FHI staff member organized and held a session on FP/HIV Integration at USAID's Global Health Bureau Mini-University. Presentations highlighted new data from operations research on FP/VCT service integration in Kenya, and key programmatic, research and advocacy gaps and challenges facing the field of integration.
- In November 2005, Wilcher participated in the Repositioning Family Planning Program Task Force Meeting organized by USAID.
- In November 2005, four FHI staff participated in the semi-annual meeting of the Family Planning and HIV/AIDS Integration Working Group. One staff member presented new data on the fertility desires of VCT and PMTCT clients. Wilcher also worked closely with the Policy Project to coordinate the participation of field-based HIV/AIDS advocates in this meeting of the working group.
- In December 2005, Wilcher gave a presentation at the American Public Health Association conference on the process FHI, the Kenyan Ministry of Health, and other partners have undertaken to integrate family planning services into VCT centers countrywide. The presentation was part of a session entitled, "Integration of Family Planning and HIV/AIDS Services."

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In January 2006, a national meeting on FP/VCT integration was held in Nigeria. This subproject supported the participation of a representative from Kenya's MOH and an FHI staff member based in Kenya, who shared experiences and lessons learned from the FP/VCT integration effort in Kenya.
- Approval to implement was obtained from USAID on February 2, 2006.
- In March 2006, a Nairobi-based FHI staff member participated in the Global Consultation on the Rights of People Living with HIV/AIDS to Sexual and Reproductive Health (SRH): Development of Policy and Programmatic Guidance.
- In May 2006, five FHI staff participated in the semi-annual meeting of the Family Planning and HIV/AIDS Integration Working Group. The technical monitor gave a presentation on FHI's module "Contraception for Women and Couples with HIV."
- The technical monitor coordinated the participation of field-based HIV/AIDS advocates in the spring working group meeting.
- In June 2006, Kenya's field-based FP/VCT integration subcommittee convened a meeting to review and finalize the country's FP/VCT integration training curriculum.
- A report documenting the FP/VCT integration process in Kenya is in the process of being finalized.
- A proposal to host a satellite session on HIV and contraception at the XVI International AIDS Conference in Toronto was submitted and accepted.
- The technical monitor and another FHI staff member wrote an article entitled, "Best Kept Secret in PMTCT: Contraception to Avert Unintended Pregnancies," which was published in the May/June 2006 issue of AIDSLink by the Global Health Council.
- The technical monitor began collaborating with FHI Research Utilization staff to develop plans for the Network of Champions under the CRTU. The Champions will focus on promoting utilization of evidence-based information around HIV and contraception.
- At the request of USAID, the technical monitor began a mapping activity with various donors funding FP/HIV integration programs and research.

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/GLP	**FCO Approved: 113104** **123100**	Sep 2005 Jan 2006
Total Approved Budget: 113104 **123100**	$	300,000 N/A	**Projected End Date:**	Jun 2008

Worldwide: Tool Kit to Increase Access to Appropriate and Effective Contraception for Clients with HIV (FCO 113106)

Technical Monitor: IYacobson
Collaborating Agency(s): Johns Hopkins/CCP; EngenderHealth
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened
Evidence-based technical assistance, curricula and tools provided to at least three field programs per year to implement, expand and improve integrated FP and HIV programs

Objective(s): 1) To synthesize information on current practices and interventions being used in integrated programs to address the RH/FP needs of women and couples with HIV; and 2) to develop a Toolkit that will include a tailored training package and other tools and job aids to increase access to contraception for women and couples with HIV.

Description: Increased access to antiretroviral (ARV) therapy and the resulting improvements in health are giving many clients with HIV a renewed optimism. Demand for contraception among clients with HIV, especially those on ARV therapy, is expected to increase. Use of effective contraception reduces the risk of pregnancy, giving women with HIV a wider range of ARV drugs. Contraception can also play a role in PMTCT of HIV by preventing unintended pregnancy.
While the evidence on "best practices" for integration of HIV/FP services is limited, it is important to offer guidance to programs/providers to move integration efforts forward. In order to do that, information on current practices and interventions will be collected through literature reviews and communication with staff in country programs implemented by FHI and possibly other partners. Additionally, rapid assessments of provider and client needs, as well as challenges in integrated programs, will be conducted in several countries with ongoing FP/HIV integration activities.
This information will be used to develop a Tool Kit that will include and adapt for worldwide audience FHI's module Contraception for Women and Couples with HIV developed in collaboration with EngenderHealth with support from USAID/REDSO/ESA. It will also include training materials tailored to providers with different technical backgrounds, needs assessment tools, facility readiness checklists, job aids for providers, and others. EngenderHealth and the Center for Communication Programs will contribute to the development of additional resources. The training materials will then be tested in at least two countries among HIV/AIDS care and treatment providers and FP providers. Following the testing and expert review of the Tool Kit, a final package will be produced and distributed in digital/CD-ROM format to CAs and other

partners involved in integrating FP and HIV services, as well as FHI's country programs where FP/HIV integration takes place.

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Activities, Accomplishments, Problems through December 31, 2005

- A workshop was held in October 2005 at the Reproductive Health Priorities Conference in South Africa which familiarized approximately 40 providers from the region with the module "Contraception for Women and Couples with HIV". This workshop also provided HI staff an opportunity to learn about the providers' experiences with integration of FP in HIV services and solicit their suggestions on what tools might facilitate integration.
- Staff also:
- Conducted a literature search to identify existing materials related to FP/HIV integration and learn about program experiences with integration.
- Identified materials that could be complimentary to the Toolkit.
- Developed a needs assessment questionnaire for providers involved in integration efforts.
- Networked with other CAs also involved in integration efforts to share and coordinate efforts (e.g. Policy Project, HIPNET, FP/HIV integration working group, Engender Health).
- Approval to implement was obtained from USAID on February 13, 2006.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Staff:
- Conducted and analyzed a rapid assessment in Kenya and initiated needs assessments in Thailand and Zimbabwe.
- Finalized the content and outline of the Toolkit and developed a first draft of the training curriculum, including objectives, training activities and session's design.
- Circulated a draft to EngenderHealth for their comments and input.
- Developed presentations on individual contraceptive methods to be used as part of the training curriculum and to compliment FP/HIV specific information provided in the existing module, Contraception for Women and Couples with HIV.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 250,000	**Projected End Date:**	Dec 2006

Africa Regional: Assessing Provision of Family Planning and Reproductive Health Services in Commercial Sector HIV/AIDS Programs (FCO 124102)

Technical Monitor: DMcCarraher

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births

Objective(s): 1) To assess if commercial sector workplace HIV/AIDS programs also provide family planning, reproductive health and child health services; 2) to document how family planning, reproductive health and child care services are paid for (private insurance's, services contracted out or work-based clinic) and the beneficiaries of them; 3) to document obstacles to providing these services; and 4) to prepare one or more case studies that highlight the commercial sectors interest in the provision of family planning as an HIV/Prevention tool. These studies will highlight commercial sector HIV/AIDS programs that also provide family planning, reproductive health and child health services or those programs that could be easily expanded to include these services.

Description: The commercial sector is an important partner for the expansion of HIV care and treatment efforts in countries with a generalized HIV epidemic. Some commercial sector businesses provide HIV/AIDS prevention and care services to their employees. These services include the provision of condoms, voluntary counseling and testing and antiretroviral treatment. However, these efforts have not been uniformly documented or synthesized. In addition, it is unknown if commercial HIV/AIDS programs provide integrated services including the provision of family planning (FP), reproductive heath care (antenatal care, delivery care, PMTCT), and child health services (immunizations and sick child visits) to their employees as well. For those programs that do provide FP and other services, the reasons for doing so, as a way to prevent HIV or as a way to improve maternal and child health, are unknown as well.
Using PEPFAR funds, Abt Associates are planning to: a) conduct a literature review of commercial sector HIV/AIDS initiatives; b) survey commercial sector HIV/AIDS programs in PEPFAR African countries and; c) prepare case studies highlighting successful commercial sector programs. Taking advantage of this opportunity, we will work with Abt to develop the survey to include questions related to FP, reproductive health (RH), and child health services. Information derived from the survey will tell us if commercial sector HIV programs are viable targets for future FP/HIV integration efforts. In addition, our GLP funding will be primarily used for the development of case studies that highlight successful commercial sector programs that already include FP, RH, and child health services or programs that are suitable for future HIV/FP integration activities.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- From March to May 2006, McCarraher worked with Abt Associates to: a) finalize the study protocol; b) develop a hard copy questionnaire that would be used when companies failed to complete the web-based survey; and c) pre-test the web-based survey and the hard copy questionnaire.

- In June 2006, the web-based survey was sent to a convenience sample of private-sector companies that have received donor support or technical assistance to implement work-place based HIV programs in Namibia, Kenya, Ethiopia, and Zambia. In each country, approximately 50 companies were identified. The companies had five days to complete the web-based survey and then were called up to five times to complete the hard copy survey. Data collection was completed on June 23, 2006, with responses received from a total of 121 companies.

Funding Source(s):	USAID - US Agency for International Development/GLP	**FCO Approved:**	Mar 2006
Total Approved Budget:	$ 114,599	**Projected End Date:**	Mar 2007

Worldwide: Follow-Up: Sharing Information on HIV and Hormonal Contraception with Global Audiences (FCO 113119)

Technical Monitor: KBest
Collaborating Agency(s): World Health Organization (WHO); National Institutes of Health (NIH)
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened

Objective(s): 1) To give policymakers, program managers, providers, and women in high HIV prevalence countries, as well as other countries, information necessary for informed decision-making about hormonal contraception; 2) to increase trust and confidence in hormonal contraceptive use, in particular, and family planning programs, in general; and 3) to bolster activities to reposition family planning in the era of HIV/AIDS.

Description: Data from an FHI-led, NICHD-funded study on hormonal contraceptive use and HIV will help answer questions about the safety of hormonal contraceptive use by family planning clients. This subproject has been a continuation of a global, multi-partner campaign to disseminate information on this subject. Activities accomplished to date include:
Support of activities and materials related to a WHO-sponsored Africa Regional Meeting held in Nairobi, Kenya, in September 2005, on the topic of hormonal contraceptive use and HIV acquisition. The meeting – funded by The Bill & Melinda Gates Foundation and by an inter-agency agreement between USAID and the NIH (FCO #3703) – was designed to bring together approximately 100 researchers, policy-makers, program managers, and women's advocates working in the HIV and RH fields to learn about the relevant scientific data and discuss the possible programmatic and policy implications.
Monitoring of media coverage of the topic.
Writing of meeting proceedings in English.
Planned activities include:
Upon publication of the FHI-led study (anticipated for late summer or fall of 2006), electronic dissemination – to more than 75,000 health decision-makers, opinion leaders, providers, and health media – of various FHI-produced background materials will occur.

Shortly thereafter, publication of an issue of Network dedicated to the topic of hormonal contraceptive use and HIV acquisition, transmission, and disease progression will occur. Distribution of approximately 61,000 copies in English, Spanish, and French is anticipated. A report of findings from a pre- and post-meeting survey conducted at the Africa Regional Meeting will be distributed to stakeholders. The survey was conducted to determine how the meeting affected participants' knowledge and attitudes about the safety of hormonal contraceptive use in regard to HIV acquisition, and to identify persistent knowledge gaps or misperceptions.

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Activities, Accomplishments, Problems through December 31, 2005

- This subproject helped to support the WHO-sponsored Africa regional meeting held in Nairobi, Kenya in September 2005 on the topic of hormonal contraceptive use and HIV acquisition. This meeting was financed by The Gates Foundation and by an intra-agency agreement between USAID and the National Institutes of Health (FCO # 3703), but monies from this subproject supplemented and leveraged that support. They helped finance FHI's key role in: 1) facilitating the meeting's organization, 2) leading a communications strategies session to prepare meeting participants to accurately present to key audiences information about hormonal contraceptive use and HIV upon return to their respective countries, and 3) writing a meeting proceedings.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A 36-page meeting proceedings, entitled "Hormonal Contraception and HIV: Science and Policy, Africa Regional Meeting, Nairobi, Kenya, September 19-21, 2005," (M2006-18) was written.
- A pre- and post-meeting survey conducted at the Africa Regional Meeting was analyzed to determine how that particular event affected participants' knowledge and attitudes about the safety of hormonal contraceptive use in regard to HIV acquisition, and to identify persistent knowledge gaps or misperceptions. A report of findings from this survey will soon be distributed to stakeholders.
- Contact with all developing country participants has been maintained (at least once every three months); updates on the expected plans for publication of the study and copies of FHI publications that would be of interest to them in their work have been provided. This activity addresses CRTU indicators, as follows: 1) Partners are involved in dissemination research results; 2) Use of information products continues post-intervention; 3) In some cases, products are distributed in response to user-initiated requests; 4) Planned goals of partnership have been achieved (i.e., communication on HIV/HC has remained balanced, not evolving into misinformation or controversy).

Findings and Outcomes:

- As of June 30 2006, three significant deliverables were generated by this subproject:
- 1) A 36-page meeting proceedings, entitled "Hormonal Contraception and HIV: Science and Policy, Africa Regional Meeting," was written.
- 2) An FHI-directed communications workshop, held at the Africa Regional Meeting, helped participants better understand how they could share accurate information with community leaders, colleagues and other health professionals, clients, and the news media upon return to their respective countries.
- 3) The pre- and post-meeting survey conducted at the Africa Regional Meeting found that a majority of respondents said post-meeting that there was no association between the use of hormonal contraception and HIV acquisition. Also, the percentage of respondents willing to prescribe, recommend, or support the use of HC by women at risk of HIV increased during the course of the meeting. Nevertheless, many had lingering concerns. They expressed a desire for more research on the topic and, in the meantime, many said they would recommend HC use only if concurrent condom use were strongly encouraged to provide dual protection against unintended pregnancy and HIV infection.

- In addition, having reviewed the results of the FHI-led study and anticipating its confidential discussion at the Africa Regional Meeting, the WHO Family Planning Guideline Steering Group issued a statement that "the study results are reassuring and that the new evidence does not modify the current guidance for contraceptive use," which states that women at risk of HIV infection or those who are HIV-infected may safely use hormonal contraception.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 191,300	**Projected End Date:**	Jun 2007

Kenya: Kenya Information Management: Hormonals & HIV (FCO 143102)

Technical Monitor: JKimani

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Research evidence provided to at least four countries to inform policy reviews and strengthen policies focused on increasing contraceptive use in HIV programs to avert HIV-positive births
International recommendations, country-specific guidelines, and program documents for contraceptive use by people at risk of HIV and HIV-infected, including women on ART changed or strengthened

Objective(s): To disseminate country-specific, evidence-based information on the relationship between hormonal contraceptive use and HIV acquisition to Kenyan stakeholders in the Ministry of Health (MOH), family planning and HIV/AIDS organizations, family planning and VCT service providers, and the media.

Description: FHI assistance for this subproject to disseminate evidence-based information on hormonal contraception and HIV was requested by the Kenyan MOH. USAID/Kenya has provided funding to support its implementation. This subproject targets a CRTU enhanced country and leverages knowledge management products on this topic being developed under a complementary subproject.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- USAID signed the approval to implement letter on January 31, 2006.
- Kenya-specific background materials about hormonal contraception and HIV acquisition were generated.
- The Contraception for Women and Couples with HIV module was disseminated at the KOGS meeting to attendees of the FP/HIV integration presentation on February 22-24, 2006.
- FHI disseminated the Contraception for Women and Couples with HIV training module at the Kenya Obstetrics and Gynecologist Society (KOGS) meeting in February 2006, enhancing partnerships and improving information flow with groups in a position to act on emerging results from FHI's work on hormonal contraception and HIV.

- FHI developed a one-page job aid on HC/HIV to supplement the Kenya FP/VCT integration training curriculum.
- FHI disseminated copies of the Contraception for Women and Couples with HIV module at the FP/HIV integration presentation at the Kenya Medical Association Annual Conference in April 2006 and at the Meeting on Sexual Health in Kenya in June 2006.
- Due to a delay in the publication of the study results on hormonal contraception and HIV acquisition, staff initiated discussions with USAID/Kenya to reprogram funds no longer needed for this subproject to other field support funded subprojects in Kenya.

Funding Source(s):	USAID - US Agency for International Development/Field Support	**FCO Approved:**	Dec 2005
Total Approved Budget:	$ 50,000	**Projected End Date:**	Dec 2006

Kenya: Examining the Family Planning Needs of Women Traditionally Targeted for HIV/STI Services (FCO 124100)

Technical Monitor: THoke

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three strategies targeted to specific populations and implemented by HIV and/or FP providers developed, evaluated, and introduced into programs in five countries.

Objective(s): To identify strategies for heightening sex workers consistent use of highly effective family planning methods by: exploring sex workers fertility desires, knowledge, attitudes and practices related to contraception; examining obstacles sex workers' face in accessing family planning services; and gathering sex workers views on how family planning services could be adapted to optimally meet their needs.

Description: Sex workers are commonly targeted for STI/HIV prevention interventions, but far less attention has been directed toward sex workers' family planning needs. Addressing sex workers' family planning needs is essential since they are at very high risk of pregnancy, given frequent sex with multiple partners. Preventing unplanned and undesired pregnancies can reduce multiple health risks for both the mother and the newborn. Additionally, in sex worker populations with high HIV prevalence, provision of family planning services to sex workers not desiring pregnancy is a means of preventing vertical HIV transmission, by reducing risk of unplanned pregnancy in HIV-infected women.

This cross sectional study will be conducted in two sites that have benefited from HIV/STI prevention interventions for sex workers. Data collection will consist of a survey conducted with a representative sample of sex workers (sample size to be determined, but likely no more than 300 women per site). The sampling strategy will include stratification by type of sex worker (bar-based, home-based, street-based), which will capture some of the socio-economic diversity of the population. The survey will include questions on reproductive history; fertility desires; knowledge, attitudes, and practices related to contraception; and experiences accessing family planning

services. Focus group discussions (FGDs) will be conducted to gather sex workers' views on how family planning services could be configured to meet the needs of this special population. The study results will be shared in a one-day workshop with program managers responsible for interventions targeting populations at high risk for STI/HIV. Workshop participants will be guided in drawing conclusions from the study results and developing possible strategies for addressing unmet need for family planning services targeting those populations, and sex workers in particular.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A literature review was completed in June 2006 as background material for the study protocol.
- The technical monitor collaborated with FHI/Nairobi in identifying field partners who could provide access to two sex worker populations: Lifebloom Services International, which works in Naivasha, and the International Centre for Reproductive Health, which intervenes with sex workers in Mombasa.

Funding Source(s):	USAID - US Agency for International Development/GLP	**FCO Approved:**	Jan 2006
Total Approved Budget:	$ 99,779	**Projected End Date:**	Dec 2006

Kenya: Risk of HIV and Feasibility Research Among House Girls in Nairobi (FCO 154100)

Technical Monitor: SThomsen
Collaborating Agency(s): P.C.E.A Bahati Martyrs Church, Nairobi
Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three strategies targeted to specific populations and implemented by HIV and/or FP providers developed, evaluated, and introduced into programs in five countries.

Objective(s): In the first phase of the study, the objectives are: 1) to map knowledge of HIV/AIDS, sexual experiences, behaviors and sexual networks of house girls; 2) to determine the feasibility of conducting an intervention study with house girls and/or their sexual partners; 3) to use the information gathered to develop an appropriate intervention to be implemented with the same population; and 4) to develop a protocol for an add-on intervention study, if one is deemed feasible. In the second phase of the study, the objectives will be: 1) to implement a program to raise awareness among members of the Bahati, Nairobi community about the vulnerability of house girls to HIV and unwanted pregnancies; 2) to implement a training/education program and support to a group of house girls from the same community; and 3) to see if the two programs result in changes in feelings of self efficacy, self-esteem, and risk factors for house girls in Bahati.

Description: Female domestic workers in Kenya, generally referred to as house girls, are in a potentially high-risk position due to the circumstances of their employment, their young age, and their low level of education. However, there are still many unknown factors concerning their level

of risk. For example, it is not known to what degree house girls in Kenya are sexually active or with whom they are having sex. Further, the nature of these relationships is unknown. It could be that their sexual relationships are of a non-consensual nature, which means that they will have little say in reducing their risk. Finally, there is uncertainty about what kind of intervention would be most helpful to house girls, and how it would work given that they are allowed little freedom of movement outside their place of work.

The first phase of the study employed the following data collection methods: 1) formative, in-depth interviews with house girls to elicit information on risky behavior and experience with non-consensual sex and/or violence, and to map sexual networks; 2) key informant interviews with members of the community (church leaders and HIV community workers); and 3) interviews with employers of the house girls to develop a feasible strategy to conduct the intervention and study. In the second phase, we will implement a church-based intervention to raise the awareness of community members about the vulnerability of house girls and to increase the life skills and housekeeping skills of house girls to try to impact on their vulnerabilities. The study will be a pre-post design with a control group, if possible.

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Activities, Accomplishments, Problems through December 31, 2005

- The protocol and question guide was approved by PHSC in August 2005.
- The local IRB approved the protocol in November 2005.
- Six data collectors were trained from October-November 2005.
- Data were collected from November-December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Data were analyzed in January 2006.
- A stakeholders' meeting for 20 people, including USAID was held in Nairobi in February 2006.
- A first draft of a report was finished and distributed for review in April 2006.
- Data were shared with participants in June 2006.
- Meetings were held with approximately 200 people in the church congregation to discuss the intervention from May-June 2006.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	Jul 2005
Total Approved Budget:	$ 182,000	**Projected End Date:**	Sep 2007

The safety and effectiveness of long-term and permanent methods have been well established, but they are not widely used in many parts of the world. The reasons for their limited use vary by method and by culture. For example, use of the IUD may be limited by provider biases toward nonclinical methods, safety concerns due to a lack of sterile gloves for insertion, myths such as IUDs 'migrating' throughout the body, or misperceptions about mechanisms of action. Vasectomy accounts for a modest proportion of contraceptive use only in a few countries, mostly in Asia. Female sterilization is more prevalent, but access to surgical services is limited in poorer areas, especially in Africa. Currently available implants, although they have advantages as an "adherence-free" method, have proven to be too expensive for wide-scale program use.

FHI CRTU Proposal, September 30, 2004. p.28: Long-Acting and Permanent Methods

LONG-ACTING and PERMANENT METHODS

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Uganda:	Repositioning Family Planning: Revitalizing LAPMs (FCO 113110)
Worldwide:	Global Advocacy & Stakeholder Engagement for LAPMs (FCO 113109)
Uganda:	Operations Research: Staged Training of Private Sector Midwives to Increase IUD Use (FCO 114108)
Nigeria:	Operations Research: Male Motivators Promoting Family Planning in the Nigeria Police Force (FCO 114109)
Worldwide:	Maximizing Access and Quality (MAQ) IUD Subcommittee, and FHI's IUD Checklist Production and Dissemination (FCO 113112)
Kenya:	Kenya IUD Revitalization – Transition Phase and M & E (FCO 113111)
Kenya:	Assessing the Future Role of Implants (FCO 112122)
USA:	Vas Irrigation During Vasectomy: Early Development (FCO 112113 and previously 2261/2707)
India:	Vasectomy Acceptability among Clients and Providers in Uttar Pradesh (FCO 116100)
Worldwide:	USAID Financial Support of Female Nonsurgical Sterilization Development (FCO 112107 and previously 2271)

Uganda: Repositioning Family Planning: Revitalizing LAPMs (FCO 113110)

Technical Monitor: EMcGinn
Collaborating Agency(s): Ministry of Health, Uganda; EngenderHealth (Acquire Project)
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners

Objective(s): 1) To provide technical assistance and support to the Uganda MoH in order to mobilize in-country stakeholders to undertake a revitalization of long-acting and permanent methods, particularly the IUD; and 2) to provide technical assistance to the MoH and in-country partners (e.g., ACQUIRE/EngenderHealth) in implementing evidence-based LAPM activities, and adapting and implementing lessons learned from the Kenya IUD Rehabilitation Initiative 2002-2005.

Description: Ever use of contraceptives by women in Uganda increased four-fold between 1988 and 2001, from around seven percent to 35 percent. Today, pills, condoms, and injectables dominate the method mix, and fewer than seven percent of contraceptive users have ever used IUDs, female sterilization, or vasectomy. Yet around a quarter of urban women, and a third of rural women, indicate an unmet need to space or limit births.

In response to these needs, this subproject will engage in LAPM activities (focused on the IUD) in Uganda. These are considered continuing activities which were initiated in January 2005 (see FCO 3007), when the Ministry of Health (MoH) requested FHI's technical assistance with expanding IUD access in Uganda, in collaboration with EngenderHealth's ACQUIRE Project (which received funding in October 2004 to undertake IUD revitalization activities within the context of promoting longer term and permanent methods). FHI initiated this collaboration by: 1) providing assistance to the MoH to establish a national "Repositioning Family Planning Working Group," composed of in-country stakeholders and EngenderHealth/ACQUIRE and FHI; 2) developing an addendum to the 2001 national family planning guidelines providing an evidence-based update on eligibility criteria for all methods; and 3) providing technical assistance to EngenderHealth on costing and monitoring and evaluation of their LAPM activities in the district of Mayuge, which will inform scale up in other districts.

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Activities, Accomplishments, Problems through December 31, 2005

- The Eligibility Criteria addendum to the National FP guidelines was finalized and 4000 copies were printed and handed over to the Reproductive Health Division, Ministry of Health-Uganda in December 2005.
- Four continuing medical education (CME) workshops were conducted (Mubende, Luwero, Arura, and Lira) in April 2006. Approximately 175 providers were reached.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 10, 2006.
- Staff supported the MoH in its efforts to coordinate the Repositioning Family Planning Working Group. Quarterly working group meetings were held in February and June 2006.

- In April 2006, FHI staff engaged professional associations through four continuing medical education (CME) workshops in four districts (Mubende, Luwero, Arua and Lira). During these workshops, staff promoted and distributed the National Guidelines addendum and FHI's IUD, DMPA and COC Checklists.
- Staff continued providing costing support to ACQUIRE/EngenderHealth. Dr. Blaakman traveled to Uganda in February 2006 to continue cost data collection and analyses in Mayuge district. He worked with Ms. Maria Najemba to identify activities and resources in Mayuge. Dr. Blaakman also met with Engenderhealth staff (Henry Kakande and Julie Wiltshire) to explore the use of the costing instrument in Hoima and Sembabule districts.

Findings and Outcomes:

- Finalizing the addendum is seen a milestone as it will equip service providers with up-to-date information on eligibility criteria for contraceptive methods. It gives clear direction on the contraceptive methods to prescribe for HIV positive clients. The addendum was disseminated during the continuing medical education meetings in April 2006.
- Support to the quarterly working group meeting has been productive and appreciated. It has provided a forum through which key players in family planning can update one another and synergize resources. The Mission has requested FHI continue this coordination role under its Focus Country Program.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 175,000	**Projected End Date:**	Jun 2007

Worldwide: Global Advocacy & Stakeholder Engagement for LAPMs (FCO 113109)

Technical Monitor: CLasway
Collaborating Agency(s): EngenderHealth
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners

Objective(s): 1) To broaden advocacy messages beyond IUDs, and to ensure that "Repositioning Family Planning" efforts include a revitalization of LAPMs based on evidence and best programming practices; and 2) to engage in-country stakeholders on revitalization of LAPMs and support champions for south-to-south learning of best practices on LAPM revitalization efforts.

Description: Despite the Cairo goal to provide couples with a "full range" of family planning methods, many couples in Sub-Saharan Africa (SSA) still lack choices regarding contraception. For instance, although LAPMs are safe and cost-effective contraceptive choices, they are used less often in SSA than in other developing countries. The most underused LAPMs include IUDs, vasectomy, and implants. The aim of this subproject is to effectively influence global, regional, and national key change agents and stakeholders towards revitalizing uptake of underutilized

LAPMs in SSA. A broad advocacy effort on underused LAPMs will be carried out at both global and country level. At global level, activities will include developing evidence-based advocacy messages on LAPMs, launching a series of advocacy briefs on a variety of LAPM topics over a period of eight weeks culminating to an electronic forum discussion over the IBP ECS system. The electronic forum will be designed to provide participants with up-to-date and state-of-the-art information on what is happening in the field and will provide an opportunity for synergy between sharing global best practices and country-based experiences. Furthermore, in October 2006, an expert consultation on vasectomy will be organized to discuss future programmatic and non-clinical research needs to improve success of such programs. At country level, the focus will be on key policy makers, health and development professionals, and the private sector to not only raise their awareness and influence them to revitalize LAPMs, but also work with in-country service delivery partners to assist them in develop a strategy for LAPM revitalization in their countries. These efforts will also be complimented by South-to-South exchanges and technical assistance geared to promote knowledge transfer and adoption of best practices.

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Activities, Accomplishments, Problems through December 31, 2005

- In November 2005, preliminary discussions were held with FHI staff to discuss ideas for broadening advocacy messages beyond IUDs.
- To ensure that "Repositioning Family Planning" efforts include revitalization of LAPMs, FHI attended the USAID Repositioning Family Planning Program Task Force Meeting to better understand the strategies and activities planned under the Operational Plan and how RtoP activities could link to this key initiative.
- In November 2005, a concept was developed to solicit funding to convene a regional forum for LAPMs in Africa. Discussions were held with EngenderHealth to co-host the conference. Unfortunately, the concept was not accepted for funding in FY 06-07.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Efforts to gather evidence-based information through several mechanisms were initiated in April 2006. A trend analysis using DHS data on prevalence, method mix, fertility preferences, and determinants of use was completed and used to inform the development of an outline for a literature synthesis document on data and experiences of programs implementing LAPM programs in SSA. Two sections of this document, the case for LAPM and factors that affect method use in SSA have been completed.
- In February 2006, a south-to-south exchange was facilitated between JHPIEGO/Malawi and Kenya to learn about programmatic efforts to revitalize the IUD. JHPIEGO staff visited health facilities under the AMKENI project in Kisii to observe, first-hand, the delivery of IUD services; participated in FHI-led sessions on IUD at the Kenya Ob &Gyn Scientific Conference, allowing for discussions on IUD revitalization with the different partners of the Kenya IUD Task Force; and were provided with FHI resource documents used in the IUD re-introduction process in Kenya.
- In response to USAID's request to organize an expert consultation meeting to discuss research priorities on new vasectomy techniques, a group of FHI staff from each department was convened to discuss objectives and agenda for the meeting. Consensus was reached to have a small meeting in October 2006 and focus on future programmatic and non-clinical research needs to improve success of vasectomy programs. Discussions with EngenderHealth to co-host were initiated June 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 200,000	**Projected End Date:**	Jun 2007

Uganda: Operations Research: Staged Training of Private Sector Midwives to Increase IUD Use (FCO 114108)

Technical Monitor: RPotdar
Collaborating Agency(s): Ministry of Health, Uganda; EngenderHealth (Acquire Project); Uganda Private Midwives Association (UPMA)

Status: Canceled
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three programmatic approaches to improve service provider performance and client access to LAPMs identified and tested

Objective(s): 1) To determine if private providers can be sufficiently motivated by an informational update to subsequently increase client demand for the IUD, as demonstrated by their waiting list/referrals; 2) to determine if technical training of private providers will significantly increase IUD uptake in study areas as compared to control areas; and 3) to determine costs and cost-effectiveness of such an intervention as compared to the typical training methodology of training everyone.

Description: This subproject proposed an innovative operations research activity in partnership with EngenderHealth/ACQUIRE to test a staggered approach to provider training and client demand creation for IUDs through community-based private midwives.
As part of a nationwide revitalization of family planning project, the Uganda Private Midwives Association (UPMA) requested training for its members on IUD insertion and removal. The UPMA has over 600 members who are distributed over much of the country. The ACQUIRE project proposed to train UPMA members in its four project districts on IUD insertion and removal, demand creation techniques and business skills.
An experiment testing a staged model of training for private sector midwives was proposed. UPMA members in test districts were to be offered a first stage of training that comprised a knowledge update in collaboration with ACQUIRE and UPMA. Those midwives interested in obtaining the second-stage technical training were to be given a stated period of time to counsel clients in their catchment areas on a range of FP methods, providing clients interested in receiving the IUD with an interim method and placing them on a waiting list for insertion as part of their training program, or referring them to other facilities that are able to provide this method. Once a midwife had demonstrated an appropriate demand in her community for IUDs, she would attend a centralized training on insertion and removal of IUDs using pelvic models, conducted by ACQUIRE and a practical training would be scheduled in the midwife's regular practice facility. The study would have examined if the intervention led to an increase in demand for IUDs in the four districts.

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Activities, Accomplishments, Problems through December 31, 2005

- From October through November 2005, Rukmini Potdar reviewed FHI's subproject time frame and study design. (The original timeframe was November 2005 through August 2007). An alternative time frame of November 2005 through February 2007 was presented to UPMA and EngenderHealth.
- EngenderHealth's Project in Uganda was scheduled to end in December 2006; this would not give FHI's subproject enough time to be completed and for the results, or any impact, to be visible.
- By mutual consent, this subproject was subsequently canceled in December 2005 and the FCO closed.

Findings and Outcomes:
- The timeframe of our MOU partner's Project in Uganda did not be mesh with the time needed to implement our subproject and to generate results, resulting in cancellation of the proposed joint effort.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 192,600	**Projected End Date:**	Dec 2005

Nigeria: Operations Research: Male Motivators Promoting Family Planning in the Nigeria Police Force (FCO 114109)

Technical Monitor: JWesson
Collaborating Agency(s): EngenderHealth; COMPASS/Pathfinder
Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three effective and replicable approaches for increasing demand for LAPMs identified

Objective(s): 1) To evaluate whether male peer education successfully: (a) improves knowledge and attitudes about FP and HIV risk-reduction behaviors among uniformed services; and (b) increases FP uptake among police officers and their families; and 2) to create an integrated FP/HIV peer education curriculum for male members of uniformed services.

Description: The International Conference on Population and Development (ICPD) Program of Action states that involving men in reproductive health should receive special effort to promote uptake of family planning and gender equality. In almost every region of the world, members of the uniformed services (military and police) have been targeted for HIV prevention programs, but there are few examples in the literature of promoting FP among these populations. Conducting operations research in such a population will help build the evidence base for male involvement programs.
The Nigeria Police Force offers a unique opportunity to test a peer education intervention for reproductive health. The Force has over 325,000 men and women serving in every region of Nigeria. The males in the Force tend to have large families and as a highly mobile group, also tend to engage in high risk sexual activities. We propose to update the Nigeria Police Force Integrated Reproductive Health Program male motivators' curriculum with the latest information

and messages about FP methods, and to train male motivators using this curriculum. Motivators will also be trained to counsel on HIV risk reduction, supply condoms and provide referrals for facilities equipped to provide specific FP methods. The subproject will take place in conjunction with clinical support for RH and HIV programs provided to the Police Force by FHI (GHAIN project), Pathfinder (COMPASS project) and other implementing agencies. The EngenderHealth Men as Partners (MAP) program will assist in updating the training curriculum.

The study will select a convenience sample of intervention sites in areas that have Force Medical Service clinics with functioning FP services. To evaluate the program, knowledge and attitudes about FP and HIV risk-reduction behaviors among male and female members of the police community and uptake of FP in Police Force Medical clinics will be measured pre- and post-intervention.

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Activities, Accomplishments, Problems through December 31, 2005

- Wesson traveled to Nigeria in November 2005 to discuss study design and details for the protocol with co-investigators in the Nigeria Police Force. Deputy Commissioner (DC) Akintade will serve as the primary co-investigator for the study. She expressed her enthusiasm for our joint efforts to both improve the male motivators program and rigorously evaluate its effectiveness. Akintade also cautioned that without following the correct steps of protocol, the study would not have the necessary support to take place. A courtesy visit with the Police Inspector General is being planned.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Wesson and DC Akintade met with the Assistant Inspector General (AIG) of Police for the Medical Service in April 2006. The AIG promised his full support for the project. Rather than trying to schedule a courtesy visit with the Inspector General, the AIG recommended sending a letter requesting authorization from the Inspector General.
- FHI sent a letter requesting approval for the study to the AIG in May 2006. The AIG forwarded this letter directly to the Inspector General with a cover letter expressing the AIG's support for this subproject.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 250,500	**Projected End Date:**	Sep 2007

Worldwide: Maximizing Access and Quality (MAQ) IUD Subcommittee, and FHI's IUD Checklist Production and Dissemination (FCO 113112)

Technical Monitor: EMcGinn
Collaborating Agency(s): US Agency for International Development; Pathfinder International; JHPIEGO; Population Council; Population Services International (PSI); EngenderHealth (Acquire Project)

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners

Objective(s): 1) To support FHI's participation in a key global technical leadership group that promotes knowledge-sharing and use of best practices related to the IUD; 2) to increase accessibility of key IUD-related resources, including job aids, assessment tools, scientific articles, and advocacy materials for field-based partners; and 3) to increase dissemination and uptake of evidence-based reproductive health practices related to IUD provision (e.g., use of FHI's IUD checklist or other job aids).

Description: Recognizing that access to the IUD has the potential to expand method choice, increase the economic sustainability of family planning programs, and reduce unwanted or mistimed pregnancies, the reproductive health community has increased its focus on revitalizing the IUD. A key component of these efforts is dissemination of accurate programmatic and clinical information on IUD use. To this end, USAID has established an IUD Subcommittee as part of its Maximizing Access and Quality (MAQ) Initiative. Co-chaired by Roberto Rivera (Family Health International, OIRE) and Roy Jacobstein (EngenderHealth/ACQUIRE Project), and with secretariat support from FHI's Research to Practice Initiative, the Subcommittee's mandate is to develop collaborative CA-based projects designed to enhance global IUD use. Its membership includes a wide range of CAs with expertise in training, research, service delivery, advocacy and marketing, logistics, and communications, thus promoting a holistic approach to IUD revitalization.

This subproject will support:
FHI's participation in the MAQ IUD Subcommittee, including ongoing secretariat support and staff participation at MAQ meetings.
FHI's coordination of the collection and review of documents for an "IUD toolkit". The toolkit is a natural extension of the ongoing work of the Subcommittee and has been identified as a major component of the Subcommittee's workplan for the next two years.
FHI's contribution to the IUD toolkit, such as FHI Briefs, PowerPoint presentations, advocacy briefs, assessment tools, and in particular, the development of background information for the FHI IUD Checklist.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI Staff:
- Organized a MAQ Mini-U session and co-presented with EngenderHealth. The session was titled "Beyond the Barriers: Strategies for 'Jumpstarting' the IUD in Africa." Approximately 25 participants from USAID, other CAs, and NGOs attended.
- Co-organized with EngenderHealth a panel at APHA (December 2005). Approximately 30 people attended. The panel was titled "How I learned to stop worrying and love the IUD: Recent Evidence and Country Efforts to Revitalize a Great Contraceptive Method. Presentations included:
- IUD 'revitalization': Recent clinical findings about the IUD's high safety and efficacy, and what to do about them, given the dynamics of change in medical settings--Roy Jacobstein.
- Revitalizing the IUD: Kenya's experience--Erin K. McGinn and Violet Bukusi.,
- Polishing the image of the IUD: The marketing challenge of repositioning the IUD--Ilze Melngailis.
- Improving access to safe high quality IUD services in Indonesia--Lucas Pinxten, Siswanto Agus Wilopo, Loesje Sompie, and Enriquito Lu.
- A factorial experiment to test an "IUD detailing" intervention in Kenya--Jennifer Wesson, Alice Olawo, Violet Bukusi, Marsden Solomon, and Job Obwaka.
- Coordinated the technical and logistical aspects of developing an electronic IUD Toolkit (www.iudtoolkit.org). The website went live April 2006, its official launch is scheduled for September 2006.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 10, 2006.
- Development of the IUD Toolkit continued; INFO completed electronic interface/structure while FHI coordinated finalization of documents.
- A MAQ IUD Subcommittee meeting was held to: (1) obtain group input on the IUD toolkit website; and (2) to share information about current IUD activities among partners.
- A promotional strategy of the IUD toolkit was drafted.
- The website went "live" in April; however, finalization of content continued and translation of 12 documents in Spanish and French were initiated.
- As of June 2006, a new version of the IUD Checklist was developed and translated to four languages English, Spanish, French, and Kiswahili.
- In April 2006, electronic versions of the checklists were posted in 12 RH/FP listservs/online databases/newsletters, e-mailed to 4,439 persons present in the Online Rolodex, and five external non-FHI websites linked to the FHI website for this checklist.
- As of June 2006, a total of 11,300 laminated IUD Checklists were printed in English, Spanish, and French languages. Of these, 33% have been distributed in response to requests from Madagascar, South Africa, Benin, Cambodia, Dominican Republic, Tanzania, and Romania.
- The IUD checklist has been endorsed and co-branded by the Ministry of Health in Uganda. In-country dissemination plans for Kenya and Uganda to reach district level health providers, managers, and trainers have been developed.
- The checklist was featured at the Global Health Conference (May 06), at the Program Design, Monitoring and Evaluation (PDME) Workshop in Dar, Tanzania (Feb 06), and was included in the INFO Programs Pop Report on IUDs (March 2006) and JHPIEGO's new IUD training curriculum (April 2006).EngenderHealth has requested approximately 100 IUD checklists for promotion in three of its workshops held in Eastern and Western Africa (05-06).

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 235,000	**Projected End Date:**	Jun 2007

Kenya: Kenya IUD Revitalization - Transition Phase and M & E (FCO 113111)

Technical Monitor: EMcGinn
Collaborating Agency(s): Ministry of Health, Kenya; AMKENI; EngenderHealth (Acquire Project)
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Evidence-based LAPM programming approaches institutionalized and implemented by at least three service-delivery organizations in at least five countries through information dissemination, technical assistance, and collaboration with partners

Objective(s): 1) To develop and implement FHI's exit strategy from the Kenya IUD Revitalization Initiative (ongoing); 2) to provide technical assistance to the Kenya MoH and other partners during the leadership transition; 3) to provide focused advocacy and outreach at the national level to program managers and professional associations to disseminate the new Kenya FP Guidelines and FHI's IUD Provider Checklist; and 4) to inform the design of future IUD and LAPM revitalization efforts by comparing and contrasting the various interventions that have recently taken place in Kenya. NOTE: the fourth objective has been broadened to include a comparative assessment of all IUD reintroduction activities in Kenya.

Description: In 2002, the Kenya Ministry of Health initiated a national effort to improve contraceptive choice and promote a sustainable method mix, with a focus on revitalizing IUD use, termed the Kenya IUD Rehabilitation Initiative. In addition to providing technical support and capacity development to the MoH, FHI has collaborated with several partners on this activity, including AMKENI (EngenderHealth-led bilateral), JHPIEGO, DFID, Kenya Obstetrics and Gynecology Society, Family Planning Association of Kenya, GTZ, PRIME/INTRAH, Africa Population Advisory Committee, and the Population Council. FHI and AMKENI have successfully increased IUD use in pilot sites by approximately 200% (see FCO 3022/3432 under the CTR). Now, several organizations are scaling up the service delivery and demand creation components of the IUD Rehabilitation project. For example, EngenderHealth has received funding to expand IUD services to non-AMKENI sites, and Marie Stopes is experimenting with social marketing and franchising of IUD supplies and services.
Under this subproject, FHI will develop and implement its exit strategy. FHI has played a pivotal secretariat and coordinating role for the MoH and partners. As IUD rehabilitation in Kenya becomes main-streamed, FHI will focus its attention on technical assistance and monitoring and evaluation. Of particular need is evaluation of the effect of the various interventions thus far at a national level.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI continues to participate in the MoH-led FP Working Group, which holds quarterly meetings.
- FHI developed an exit strategy to ensure ongoing leadership by others working on IUD revitalization; IUD activities will be integrated into Kenya's new APHIA bilateral projects (with TA from EngenderHealth).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 10, 2006.
- FHI supported the Ministry of Health, Division of Reproductive Health in making a presentation of the revised Kenya FP guidelines at the Nairobi Hospital 1st Annual

Reproductive Health Symposium held on the 21st of March 2006. This forum provided a good channel through which the revised family planning guidelines for service delivery were disseminated. Similarly, this symposium was a good opportunity for public/private sector partnership. The audience at this symposium included over 200 nurses and obstetricians nationwide from both the private and public sector. About 139 copies of the guidelines were distributed among the participants and an FHI display booth was set up where various materials related to reproductive health were displayed and request forms were provided.

- Staff also:
- Distributed the FP guidelines and made a presentation during the Kenya Clinical Officers Association annual scientific conference, January 2006.
- Distributed the FP guidelines and made a presentation during the Kenya Obstetrics/Gynecologists Society annual scientific conference, February 2006.
- Collected and documented AMKENI IUD-uptake data.
- Printed and disseminated a report of the Kenya IUCD revitalization experience.
- Provided ACQUIRE's Kissii project with six boxes of IUD and FP client brochures.

Findings and Outcomes:

- Kenya's new APHIA II bilateral projects (several awarded, one in each of five provinces) will be integrating IUD revitalization efforts into their workplans, under MoH leadership and with technical assistance from EngenderHealth. This is tangible evidence that FHI's IUD revitalization effort, initiated in 2001, has become mainstreamed in Kenya's family planning and reproductive health programs.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 250,000	**Projected End Date:**	Jun 2007

Kenya: Assessing the Future Role of Implants (FCO 112122)

Technical Monitor: DHubacher

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three effective and replicable approaches for increasing demand for LAPMs identified

Objective(s): 1) To evaluate the Kenyan experience with implants; 2) to provide donors with information necessary to determine whether they should begin purchasing implants for their programs.

Description: Implants are highly effective and acceptable in many different developing countries. Unfortunately, the cost of Norplant and subsequent second-generation implants (Jadelle and Implanon) has never been low enough to make the method cost-competitive, thus limiting availability in all but a few places.

Kenya has led the African continent in the use of implant technology since its first introduction in the 1980s. Over the past several years, the Kenyan MOH has provided tens of thousands of sets of Norplant and conducted extensive training for insertion and removal. Last year, the Kenyan MOH received a donation of 20,000 sets of Jadelle, which were exhausted within six months, even in sites such as the Kenyatta National Hospital, where the government was charging $5.33 for the implants compared to only $0.67 for a three-month supply of oral contraceptives or a DMPA injection. The enthusiasm in Kenya for implants provides an important opportunity to review this country's experience and evaluate the potential role implants may play in the long-term in family planning programs across the region.
Under this subproject, a situation analysis will be conducted to assess the role that implants play in the current Kenyan program, evaluate potential demand, review factors that would promote and sustain demand in Kenya, and assess views of how implants could optimally complement the provision of other family-planning methods.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI collected information on the status of implants in Kenya through a situation analysis conducted by staff in FHI's Kenya office. The Nairobi office interviewed stakeholders, program managers, clinicians and others to learn about current provision of implants and to assess the prospects for more widespread use of implants.
- A third objective in the original report on this subproject (to assess whether the private sector can provide implants with sufficient quality and in a sustainable manner if a lower cost implant were to become available) has now been moved to a separate FCO (Implant provision through the private sector FCO 112124).

Findings and Outcomes:

- The Situation Analysis in Kenya indicated that about 75,000 implants have been inserted in the past 12 months. Users are increasingly switching from OCs and DMPA to implants. Most implant insertions are being performed in NGO and public sector facilities where cost recovery is often not a priority. However, IntraHealth, in collaboration with the Kenya Ministry of Health, recently trained 172 private sector service providers on implant provision.
- In the instances where private sector providers are inserting implants in Kenya, they are receiving the implants free of charge from the government. Thus implant provision could be profitable to the private sector because they do not have to cover commodity costs; however, provision may not be sustainable if it is dependent on a continued supply of free implants. The important question, then, is at what price-cost combination (commodity plus services) can implant provision be sustainable in the private sector. Of acute interest is to learn more about the potential of cost recovery of implant provision in the private sector, and how private sector provision might leverage public sector services.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 220,000	**Projected End Date:**	Jul 2007

USA: Vas Irrigation During Vasectomy: Early Development (FCO 112113 and previously 2261/2707)

Technical Monitor: DSokal
Collaborating Agency(s): University of Hyderabad, India

Status: Complete
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: At least one spermicidal agent that could prove effective in hastening azoospermia after vasectomy evaluated

Objective(s): (1) To conduct one or more Phase I studies to determine the potential efficacy of a new approach to vas irrigation, which would be an improvement of the standard no-scalpel vasectomy procedure; (2) to conduct animal studies to test the hypothesis that diltiazem causes an effect on sperm in vivo; (3) to determine if irrigating with a spermicidal solution causes an effect on sperm counts; and (4) to conduct other vasectomy-related activities.

Note: The fourth objective was added with the approval of OYB funds for FCO 2707 and only applies to activities that will be conducted under this FCO.

Description: Over the past 25 years, vas irrigation has been proposed by various urologists as an improvement to the vasectomy procedure. This technique flushes sperm from the vas and should shorten the time to azoospermia following vasectomy. However, vas irrigation has never been seriously studied. FHI data from a survey of urologists showed that 90 of 177 pregnancies after vasectomy (50.8%) were attributed to non-compliance or failure of a backup method in the immediate post vasectomy period. These data suggest that the problem of the downstream sperm deserves more attention. FHI has identified several spermicidal agents that appear well-suited for vas irrigation. The spermicidal activity of these agents has been evaluated by CONRAD. Based on CONRAD's evaluation and other data, discussions will be held with the USFDA as needed, and a plan for a Phase I study of the lead compound will be developed.

NOTE: In January 2002, USAID requested a scaled back version of this subproject to cover early development work only at this time.

FCO 2707 was established specifically to handle funding from NICHD through an interagency agreement. This funding was obtained following a favorable review of an Indo-US grant application to support research on vas irrigation.

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Activities, Accomplishments, Problems through December 31, 2005

- USAID approved the subproject December 2000.
- A patent application covering two compounds, methylene blue and diltiazem, as vas irrigants, was filed.
- Two medically trained interns worked on two analyses: 1) FHI's survey data of US urologists; and 2) cost-effectiveness of vas irrigation.
- In fall 2001, a dose-ranging animal study using diltiazem as a vas irrigant was conducted at the University of Hyderabad.

- In October 2002, D Sokal and PRK Reddy visited India to explore the potential for vas irrigation-related research in India. They also looked for labs able to conduct animal safety studies under Good Laboratory Practice.
- A second animal study to assess in-vivo efficacy of diltiazem on rat sperm was conducted in the winter of 2002 in Hyderabad.
- A Pre-IND packet was submitted to the USFDA June 2003, and a Pre-IND teleconference was held July 2003.
- Vimta was chosen to implement a study in rabbits looking at acute local toxicity of diltiazem for vas irrigation.
- NICHD funds targeted for this work were provided September 2003 (FCO 2707).
- In December 2003, D Sokal visited Pallu Reddanna at the University of Hyderabad to discuss work plans on the Indian side of the Indo-US grant.
- Redanna received notification of funding of the Indo-US grant, began planning work for his part of the research, and visited FHI September 2004.
- A dose-ranging study of diltiazem's local toxicity in rabbits was conducted at Pallu Reddanna's lab funded under the Indian site of the Indo-US grant.
- D Sokal and Pallu Reddanna attended a conference, “The Future of Male Contraception,” held in Seattle in fall 2004.
- FHI revised the final protocol for the GLP study of diltiazem in rabbits, and sent it to the FDA. After resolving questions, the FDA gave approval for study initiation without further review.
- In December 2004, Dr. Sokal met with Vimta Labs officials in Hyderabad to discuss the planned GLP study of diltiazem’s local toxicity, and met with Pallu Redanna at the University of Hyderabad to discuss work plans on the Indian side of the Indo-US grant.
- The in-life portion of the GLP study of diltiazem in rabbits was initiated June 2005 and was completed July 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The histological and biochemical analyses were completed. Vimta sent the draft final report to FHI for review in April 2006.
- After review by FHI and revisions by Vimta, the final report was completed in June 2006.

Findings and Outcomes:

- The pregnancy rate after vasectomy (as indicated by data from a sample of urologists in the United States) is about 1 per 1,000; and about half of those pregnancies are conceived almost immediately after the vasectomy procedure (Deneux-Tharax et al., 2004, full citation below).
- Vas irrigation with a spermicidal agent such as diltiazem appears to be a potentially cost-effective alternative to the current approach of no irrigation, or irrigation with normal saline, for preventing pregnancy following vasectomy (unpublished).
- The first dose-range finding toxicology study showed that diltiazem injection inside the vas is tolerated by rats up to a dose of 50mg/kg body weight.
- A second non-GLP study showed that diltiazem causes an effect on sperm in-vivo and significantly affects the viability of sperm.
- Two papers related to vas irrigation have been published:
- Wood BL, Doncel GF, Reddy PR, Sokal DC. Effect of diltiazem and methylene blue on human sperm motility, viability and cervical mucus penetration: potential use as vas irrigants at the time of vasectomy. Contraception, 2003 Mar; 67 (3):241-5. FHI Pub #2003-16.
- Deneux-Tharaux C, Kahn E, Nazerali H, Sokal DC. Pregnancy rates after vasectomy: a survey of US urologists. Contraception. 2004 May; 69(5):401-6. FHI Pub #2004-16.
- The GLP study of a single dose of diltiazem for vas irrigation in rabbits showed that:
- Irrigation of the vas with Diltiazem at three dose levels, from 0.2 to 1.0 mg per vas, did not cause any adverse systemic effects.

- The histological observations of urogenital organs namely vas, seminal vesicle, urinary bladder and prostate showed that Diltiazem injection during vasectomy caused local toxicity in the vas and seminal vesicles at all dose levels. No histological changes were seen in specimens from the prostate or bladder.
- In conclusion, vas irrigation at three dose levels caused local toxicity as evidenced by histological changes, particularly in the epithelium of vas (both left and right) and seminal vesicle.

Funding Source(s):			USAID - US Agency for International Development/Core; USAID - US Agency for International Development/OYB	**FCO Approved:**	**2261**	Nov 2000
					2707	Sep 2003
					112113	Aug 2005
Total Approved Budget:	**2261**	$	416,180	**Projected End Date:**		Jun 2006
	2707	$	50,000			
	112113	$	42,856			
		$	509,036			

India: Vasectomy Acceptability among Clients and Providers in Uttar Pradesh (FCO 116100)

Technical Monitor: GGuest
Collaborating Agency(s): EngenderHealth
Status: Ongoing
Group: BASS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: At least three effective and replicable approaches for increasing demand for LAPMs identified

Objective(s): To establish evidence-based guidelines for improving vasectomy uptake in Uttar Pradesh and other states of India, as well as other counties within the region.
This subproject will expand upon previous vasectomy research work done in other regions, and ultimately improve understanding of the barriers to vasectomy uptake.

Description: Over the past decade, calls have been made on several fronts to involve men more in matters of reproductive health and family planning. One way to better involve men in family planning is to promote male-oriented methods of contraception thereby giving couples more contraceptive choices. Vasectomy has long been recognized as a highly effective method of contraception. Compared to female sterilization, vasectomy is more convenient, less expensive, and safer. Despite the many benefits of vasectomy, it remains an under-utilized method of contraception. Sterilization is the most widely used contraceptive method worldwide, yet female sterilization accounts for the majority of procedures, more than five times that of vasectomy. Vasectomy accounts for only 7% of all modern contraceptive use at the global level. In the majority of less-developed countries, this figure drops to less than 1%. In India, female sterilization outnumbers male sterilization by a factor of 18 to 1 nationwide, and in Uttar Pradesh, this ratio is more than 100 to 1.

This subproject will be a collaborative venture between FHI and EngenderHealth, and will take place in two geographically distinct districts of Uttar Pradesh - Ballia and Meerut. The study will investigate vasectomy acceptability from both the supply and demand sides of the equation and will collect data from vasectomy clients and their wives, potential vasectomy clients and their wives, tubal ligation clients and their husbands, family planning providers, and public health stakeholders.

The study methodology includes: secondary data analysis and synthesis, focus groups, in-depth interviews , observation, and a structured survey. The study will involve approximately 285 participants. The analytical approach will triangulate all data sources. Findings from this study will be given to government officials of Uttar Pradesh to be fed into the design of ongoing programs.

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Activities, Accomplishments, Problems through December 31, 2005

- A draft protocol was written in November 2005.
- Guest and Bunce traveled to India between December 7-16, 2005 and met with government officials, the USAID mission, local research organizations, and representatives from various family planning stakeholders (UNFPA, SIFPSA, Population Council).
- A local implementing agency--EngenderHealth--was identified to do the research. A verbal understanding of the arrangement was reached on December 15, 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A subagreement was signed with EngenderHealth, India in May 2006.
- The protocol was revised based on information obtained during the December trip.
- USAID signed the approval to implement letter on March 31, 2006 (India Mission) and April 10, 2006 (DC office)
- The protocol was submitted to PHSC and obtained conditional approval on April 12, 2006. PHSC approval is conditional upon local IRB approval.
- Data collection instruments were developed.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	$ 432,207	**Projected End Date:**	Jul 2007

Worldwide: USAID Financial Support of Female Nonsurgical Sterilization Development (FCO 112107 and previously 2271)

Technical Monitor: ACancel

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: An FDA-regulated Phase II clinical trial of a nonsurgical female sterilization method will be underway and negotiations with a private sector licensee will be initiated

Objective(s): To support the development of a method of non-surgical female sterilization.

Description: FHI received a grant from a private foundation to develop a nonsurgical female sterilization method; this foundation only pays 15% of FHI's overhead (G&A) expenses.
Under this subproject, USAID will provide financial support to cost share the G&A expenses for FCOs 1656, 1340, 1330 and 1663. These FCOs include activities related to: 1) the development of erythromycin as a means of female nonsurgical sterilization; and 2) the operations of a consumer advisory committee which provides oversight of the overall female nonsurgical sterilization program.
As a management FCO, this subproject will not routinely be reported.

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Activities, Accomplishments, Problems through December 31, 2005

- After a private foundation informed FHI that they would only pay 15% overhead, a request was made by FHI Senior Management to USAID for financial support. USAID agreed to pay the difference in overhead effective March 2001.
- A letter was sent to USAID in November 2001 requesting written approval for the use of USAID core funds to pay FHI's portion of the overhead. Approval was granted in December 2001.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Updates for this FCO are summarized in EIS reports for FCO 1656, 1658, 1339, 1340 and 1390.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved:** **2271**	Apr 2002
			112107	Jul 2005
Total Approved Budget: **2271**	$	156,619	**Projected End Date:**	Apr 2010
112107	$	351,445		
	$	508,064		

Now that the spermicide nonoxynol-9 (N-9) has been ruled out as a microbicide, attention has shifted to other substances that might be used topically as a protective barrier against HIV and other sexually transmitted infections (STIs). An effective vaginal microbicide would offer a desperately needed option for women at risk of HIV who cannot persuade their partners to use condoms.

More than 50 agents are being studied for their microbicide potential, and about one-third are in clinical (human) trials. While a microbicide is unlikely to reach the market until after 2010, six microbicide products are expected to enter effectiveness trials—the most advanced stages of testing in humans—in 2003 and 2004, says Dr. Zeda Rosenberg, chief executive officer of the International Partnership for Microbicides (IPM) and former FHI scientific director for the HIV Prevention Trials Network (HPTN), a worldwide collaborative research program that evaluates HIV prevention interventions.

Network, Vol. 22, No. 2, 2003: Barrier Methods

MICROBICIDES

Strategic Objectives

- To support the development of vaginal microbicides through the multiple phases of clinical trials, including, as appropriate, conducting trials to determine a product's contraceptive effectiveness.
- To increase understanding of social and behavioral issues associated with microbicide use in both clinical and non-clinical trial settings.
- To ensure that trial results, both positive and negative, and other evidence-based knowledge of microbicides are readily made available to research study participants, relevant international bodies, policy makers, practitioners and potential clients, and to provide technical assistance in utilizing findings and evaluating impact of microbicide research.

FHI/NC subprojects fully or partially funded by USAID's CTR Agreement:

Benin:	CONRAD: Phase III Trial of CS Gel in Multiple Countries (FCO 12019 and previously 1785/2294)
Worldwide:	Behavioral Support for CONRAD Phase III Trial of Cellulose Sulfate (CS) (FCO 12018 and previously 1786/9517)
Nigeria:	HPV Add-On to Randomized Controlled Trial of Cellulose Sulphate (CS) Gel (FCO 2298)
USA:	Safety of Citric Acid (FCO 2295/132110)
Worldwide:	Site Development for Microbicide Studies (previously FCO 2267)
India:	Indo-US Collaborations on STIs and RTIs (FCO 2702 and previously 7702)

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Nigeria:	Savvy Phase III RCT (FCO 2277/132104)
Ghana:	Savvy® Phase III RCT (FCO 2278/132105)
South Africa:	South Africa: Microbicides: Carraguard Phase III Trial Interim Analysis for DSM (FCO 139100
Nigeria:	Randomized Controlled Trial of Cellulose Sulfate (CS) Gel and HIV in Nigeria (FCO 2266/132100)
South Africa:	RCT of Tenofovir Gel in South Africa (FCO 132108)
South Africa:	Safety and Feasibilty of the Diaphragm Used with ACIDFORM (FCO 2276/112103)
South Africa:	Acidform Behavioral Data Analysis (FCO 116101)
USA:	Phase I Study of the BufferGel Duet's Functional Performance, Safety and Acceptability (FCO 2292/132102)
India:	Sustained Acceptability of Vaginal Microbicides: Male and Female Perspectives (FCO 136100/116105 and previously 9386)
USA:	New Delivery Device for Vaginal Microbicides (FCO 1844/132103 and previously 2290)
USA:	Development of a Phase II Microbicide Trial Protocol (FCO 132107)
Worldwide:	Independent Monitoring of CONRAD Collaborative Studies (FCO 2285/132101)
USA:	Meeting on Pregnancy in Microbicide Studies (FCO 132106/172001)
USA:	Statistical Support – Microbicides (FCO 139101)

Benin: CONRAD: Phase III Trial of CS Gel in Multiple Countries (FCO 12019 and previously 1785/2294)

Technical Monitor: JCaraway
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate

Objective(s): To assess the effectiveness of cellulose sulfate (CS) gel (3.5 ml) compared to placebo gel (3.5 ml) in preventing vaginal male-to-female transmission of HIV. The secondary objective is to assess the effectiveness of CS gel (3.5 ml) compared to placebo gel (3.5 ml) in preventing vaginal male-to-female transmission of N. gonorrhoeae and C. trachomatis.

Description: This is a Phase III, multi-center, randomized, placebo-controlled, blinded, two-arm study that will enroll 2,574 HIV-negative women at high risk of HIV acquisition through heterosexual intercourse. The study will be conducted in six countries (Benin, Burkina Faso, India, South Africa, Uganda and Zimbabwe) at seven different sites (two sites in India: Chennai and Bangalore). The study will include 12 months of participant recruitment per center and 12 months of follow-up per participant. The participants will be instructed to apply their assigned gel in the vagina within one hour before each act of vaginal intercourse. Screening, enrollment and follow-up for the entire study are expected to last approximately 28 months in each site. Remote data entry, in-country clinical monitors and in-country research assistants will be used at all sites with the exception of the South Africa site which will ship forms to FHI for data entry.
Formative pre-trial preparatory work was done by BASS staff under FCO 9517 and ongoing behavioral work to assist the conduct of the trial is being done by BASS staff under FCO 12018.
NOTE: FHI is providing data management, statistical analysis, clinical monitoring, and behavioral research support for this study. In addition, some limited regulatory support is provided. This study, which was previously sponsored by CONRAD (FCO 1785) and USAID (FCO 2294), is now supported with funding from USAID microbicides and The Bill and Melinda Gates Foundation provided to FHI via contracts with CONRAD. The FCO for the clinical portion is 12019 and the FCO for Behavioral work is 12018.

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Activities, Accomplishments, Problems through December 31, 2005

- Preliminary planning was conducted with GMP funds from CONRAD (FCOs 1772 and 1785).
- In February 2004, a protocol development meeting was held in Washington, DC and CONRAD submitted the protocol to USAID.
- CONRAD submitted the protocol to the Eastern Virginia Medical School (EVMS) IRB for approval in May 2004.
- Funding was transferred from CONRAD (FCO 1785) to USAID (FCO 2294) in August 2004. A Transfer of Obligations and a Memorandum of Understanding (MOU) were finalized in September 2004, and a contract was initiated in July 2006 between FHI and CONRAD.
- The Data Monitoring Committee plan was finalized in January 2005.
- The Case Report Forms (CRFs) were finalized in February 2005 and select CRFs were amended in November 2005.
- A sixth site was identified in Bangalore, India (BA) in March 2005, and a seventh site in Harare, Zimbabwe was selected in May 2006.
- The statistical analysis plan was finalized in April 2005.

- Comprehensive trainings were conducted in South Africa (SA) and Uganda (UG) (April 2005), Benin (BE) and Burkina Faso (BF) (June 2005), Chennai (CH) (August 2005) and BA (March 2006). Refresher trainings were conducted in UG (July 2005), BE (September 2005), CH (February 2006) and BF (June 2006).
- In May 2005, the study manual and the monitoring plan were finalized. The monitoring plan was subsequently amended in July 2005 and December 2005.
- The data entry system was validated in June 2005.
- The first protocol amendment (version 1.1) was approved by EVMS as well as by IRBs in SA, UG, BE, BF and CH. The second amendment (version 2.0) was approved by the EVMS IRB in spring 2006.
- Study gels were shipped to SA, UG, BE, and BF in June 2005, CH in July 2005. Second shipments were also sent to SA, UG, BE, BF, CH and BA in spring 2006.
- SA and UG began recruitment in July 2005, BE in August 2005 and CH in February 2006.
- Multiple monitoring visits were conducted by FHI monitors and by ICRAs in SA, UG, BE and CH.
- The second investigators' meeting was held in Amsterdam in October 2005.
- Audits were conducted in Benin in November 2005, in Uganda in December 2005, and in South Africa in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Two of the ICRAs attended monitoring training in Nairobi, Kenya in January 2006.
- The Monitoring Plan was amended in January 2006.
- The Chennai, India site began recruiting participants in February 2006.
- CONRAD, FHI and ITM study staff provided behavioral, data management, laboratory, GCP/ethics and core study training to the Bangalore site team in March 2006.
- A protocol amendment was approved by the CONRAD IRB to include the following changes: 1) contraception will be offered to enrolled women (except in Bangalore where it is not allowed), 2) female condoms will be made available to all women where appropriate, 3) the language was clarified regarding when it is allowable for participant to resume gel use after a pregnancy, and 4) venous blood will be collected (instead of fingerprick) blood for confirmatory testing when indicated during follow-up.
- The protocol for the ongoing behavioral clinical trial support work was approved by FHI's PHSC in March 2006 and site IRB submissions followed.
- A revised Study Manual v2.0 was issued to all sites.
- An additional Case Report Form (CRF) was developed, and a plan for implementing BED testing in Chennai and Bangalore (as required by BMGF) was developed.

Funding Source(s):		CONRAD/Collab. Agency; USAID - US Agency for International Development/Core		**FCO Approved:**	**1785**	Apr 2004
					2294	Aug 2004
					12019	Jul 2005
Total Approved Budget:	**1785**	$	113,144	**Projected End Date:**		Aug 2009
	2294	$	2,664,868			
	12019	$	6,210,285			
		$	8,988,297			

Worldwide: Behavioral Support for CONRAD Phase III Trial of Cellulose Sulfate (CS) (FCO 12018 and previously 1786/9517)

Technical Monitor: CGeary
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: BASS

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested

Objective(s): To improve the quality and the operations of CONRAD's Phase III clinical trial of cellulose sulfate (CS) as a microbicidal agent by developing empirically grounded strategies to: 1) increase participant recruitment and retention; 2) improve adherence to study protocol, including product use and attending regularly scheduled clinic visits; 3) implement a comprehensive informed consent process designed to increase participants' understanding of informed consent; and 4) determine local community attitudes about the upcoming trial, and develop and implement strategies to improve community support throughout the course of the trial.

Description: CONRAD requested a partnership with FHI/BASS to conduct behavioral activities for their proposed Phase III Clinical trial to test the effectiveness of cellulose sulfate (CS) as a microbicidal agent to prevent HIV among high-risk women (women with multiple partners). The planned sites were Benin, South Africa, Uganda, Chennai and Bangalore India. Burkina Faso was subsequently added. Initially, the behavioral work in support of the CONRAD Phase III Trial of CS was included under FCO 1786. The behavioral work was then included under FCO 2294, which also included all FHI work in support of the CONRAD Phase III Trial of CS: BIOS, Data Management, BASS and Clinical Monitoring.
In December 2004, it was decided the behavioral objectives and costs were sufficiently distinct to be assigned a separate FCO (9517) and subproject. FCO 9517 was closed on June 30, 2005 and the new FCO 12018 was assigned. Behavioral fieldwork will begin at least 6 months prior to clinical trial initiation of FHI Study# 9845 and be carried out over 6 –10 months at each of the 6 sites. The behavioral teams will provide ongoing community monitoring during the course of the clinical trial and will assist the clinical team in addressing any issues related to recruitment/retention. Initial tasks center on conducting meetings and interviews with relevant stakeholders at each site. Staff will next convene focus group sessions with community groups/stakeholders. Findings will be used to develop instruments to be used in focus groups with past and potential trial participants. The outcome of the study will be recommendations to CONRAD for approaches to: (1) improve recruitment and retention; (2) foster community support; (3) monitor informed consent comprehension; and (4) develop strategies, if needed, for early trial exit.

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Activities, Accomplishments, Problems through December 31, 2005

- The scope of work was approved by CONRAD in April 2004.
- A subagreement (9517-1) was negotiated with the Institute of Public Health at Makerere University in Kampala, Uganda.
- Subagreements were negotiated with Centre Hospitalier in Benin and Medical Research Council in South Africa (9517-2 and 9517-3 respectively).
- On December 17, 2004, CONRAD decided to add an additional Asia site, and cut back on Africa sites; therefore, the Kenya site was dropped.

- In January 2005, Betsy Tolley traveled to Benin for data collection training of the Benin and Burkina Faso preparedness teams, and Cynthia Woodsong traveled to Uganda for material development and discussion of the informed consent booklets.
- Subagreements were negotiated with Centre Muraz in Bobo-Dioulasso, Burkina Faso and YRG CARE in Chennai, India (9517-4 and 9517-5, respectively).
- Tolley traveled to Chennai, India for data collection training in March 2005.
- FHI's BASS staff and site behavioral teams conducted trainings in recruitment/retention strategies and the informed consent process at the clinical trial trainings in Uganda, South Africa, Benin and Burkina Faso in April and May 2005.
- The informed consent flipbook and instruction for gel use sheet were finalized.
- CONRAD announced the addition of a 6th site, India-Canada Collaborative HIV/AIDS Project (ICHAP) in Bangalore, India.
- An on-going BSS Monitoring Plan was shared and approved by Lut Van Damme and sent to sites for development of site specific work plans in June 2005.
- The ongoing BSS Protocol was approved by PHSC in August 2005.
- Tolley and site behavioral teams conducted training in recruitment/retention strategies and the informed consent process at the clinical trial training in Chennai in August 2005.
- FHI staff traveled to the Investigators' Meeting in October 2005.
- Tolley traveled to South Africa for a monitoring visit in October 2005.
- CONRAD approved the BASS contract in November 2005.
- Tolley traveled to Bagalkot, India to meet with the clinical trial team to develop and assess preparedness and BSS monitoring plans in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Subagreements in Benin, Chennai, Uganda and South Africa were extended in January 2006, and FHI staff traveled to these sites to develop site specific BSS plans, provide additional training and monitor the studies.
- A subagreement was negotiated with St. Johns Medical College in Bangalore, India for the on-going BSS Monitoring. However, due to staffing issues, the subagreement has been put on hold.
- Tolly participated in the clinical trial site initiation training for the Bagalkot site in March 2006.
- FHI staff and site behavioral teams attended the Microbicide 2006 Conference in South Africa in April 2006.
- An amendment to the on-going BSS Monitoring Protocol was submitted to PHSC in June 2006. Local IRB submissions were made in Chennai, Burkina Faso and Canada (for the Benin site). Approvals were received from Chennai and Canada/Benin IRBs in June 2006.

Funding Source(s):		CONRAD/Collab. Agency; USAID - US Agency for International Development/Core		**FCO Approved:**	**1786**	Apr 2004
					9517	Dec 2004
					12018	Jul 2005
Total Approved Budget:	**1786**	$	80,000	**Projected End Date:**		Jun 2008
	9517	$	4,322,000			
	12018	$	1,695,745			
		$	6,097,745			

Nigeria: HPV Add-On to Randomized Controlled Trial of Cellulose Sulphate (CS) Gel (FCO 2298)

Technical Monitor: KNanda
Collaborating Agency(s): CONRAD
Status: Canceled
Group: CRD

Objective(s): 1) To evaluate the effect of CS on the incidence of HPV infection; and 2) to evaluate the effect of CS on persistence of HPV infection.

Description: Genital human papillomavirus (HPV) infections cause over 99% of squamous-cell cervical cancer. Cellulose Sulfate (CS) was recently shown to strongly inhibit HPV in vitro. This add-on study to study # 9757 presented a unique opportunity to understand the potential role of CS on HPV infection among women. If CS could have been shown to prevent HPV, it would have been a useful tool in the battle against cervical cancer. Because it was planned to be an add-on to an existing study, the add-on study was expected to be conducted relatively inexpensively and quickly. The primary study would have been a randomized controlled trial of 2,160 women, aged 18-35 at high risk for HIV, who were followed for one year of study participation. Half the women would use CS gel, and half would use a placebo gel. The HPV add-on study was planned to begin approximately three months after the main study began, and hoped to enroll 2000 women.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI hired a consultant to help with the study. The consultant negotiated with several laboratories to get the best pricing on HPV testing.
- The protocol was drafted and submitted to PHSC for approval. PHSC did not grant approval, requiring instead that the protocol for study 9757 (see FCOs 2266 and 132100) be amended.
- The FCO and subproject were closed in October 2005.

Findings and Outcomes:

- Due to difficulties in amending the main study protocol, FHI decided not to pursue this add-on study.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Apr 2005
Total Approved Budget:	Canceled	**Projected End Date:**	Oct 2005

USA: Safety of Citric Acid (FCO 2295/132110)

Technical Monitor: GPittman
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

Objective(s): To provide statistical and data management support for a CONRAD study to determine the safety of citric acid as an agent in preventing STD and HIV infection.
NOTE: While originally the title and objectives of this subproject referred to safety and acceptability, the design of the study was narrowed to focus on the safety of lime juice as a vaginal product.

Description: The study consisted of 48 women divided into 4 treatment groups; 47 were enrolled. The study was conducted at two centers. The study was a Phase I, crossover (for application method), controlled, randomized study in healthy women aged 18-50 with regular menstrual cycles and willing to abstain from intercourse during their participation in the study. The study was to assess the safety of intravaginal lime juice in three concentrations or plain water after six consecutive days of twice-daily application. The test fluids were applied two ways: (1) douching; and (2) within a modified tampon using a tubular plastic applicator. Participants applied 24 ml of their assigned fluid (undiluted lime juice, lime juice diluted with water to a 50% concentration, lime juice diluted with water to a 25% concentration, or plain water) twice daily for 6 consecutive days. In one menstrual cycle, the test fluid was applied via douche. In the other, it was applied with the modified tampon device. All women were clinically evaluated by naked eye exam, colposcopy, and cervicovaginal lavage at baseline, on day 3 (after the fourth application), and after the last application in each cycle. In addition, women were clinically evaluated by naked eye exam and colposcopy one hour after the first application in each cycle. A substudy (FHI study #9905) was also conducted in which a subset of participants from each site (16 total) were interviewed in-depth regarding their experiences with the modified tampon.
NOTE: FHI is providing biostatistical and data management support for this CONRAD study. FHI conducted the in-depth interviews with selected participants and provided data analysis for the substudy.
This activity is funded with USAID monies designated for microbicide research. FCO 2295 was included in the CTR No-Cost Extension through June 30, 2006. Additional money to complete the clinical study was approved under the CRTU microbicide funds, FCO 132110, effective July 1, 2006.

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Activities, Accomplishments, Problems through December 31, 2005

- USAID granted preliminary approval of this subproject in September 2004.
- The design of this study was influenced both by the findings of ethnographic research (FCO 9516) and the recognized urgency of learning if the use of lemons/limes as vaginal products is safe.
- The protocol was finalized in January 2005, and amended in March 2005.
- CRFs were developed by CONRAD, reviewed by FHI, and finalized in April 2005.
- The data management plan was developed and approved.
- The clinical study was initiated in May 2005.
- A protocol, informed consent, fact sheet and interview questions were written and approved by FHI's PHSC for conducting the in-depth, qualitative research substudy with citric acid participants who used the modified tampon for application of lime juice.
- The revised protocol (which included the addition of the substudy) was submitted to the IRB's of EVMS and Magee Women's Hospital.
- Interviewers were trained in the conduct of the substudy.
- The substudy was completed and the data analyzed in October 2005.

- Recruitment ended in December 2005.
- All data, except cytokine data, were received in-house in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006
- The sites were closed between January and February 2006.
- All medical coding and adjudications were completed. All querying on clinical data as needed for initial presentations at Microbicides 2006 was completed.
- A data freeze of all data except for cytokines was made in late February 2006.
- All key variables were independently verified on blinded data, and study was unblinded on March 3, 2006.
- Analysis was completed in time for CONRAD to present key findings at the Alliance for Microbicides Development meeting in March 2006 and a more detailed presentation at the Microbicides 2006 meeting in April.
- Data entry and querying, including cytokine data, were completed in May 2006.
- The final data freeze was completed in May 2006.
- Analysis of the cytokine data was completed and the final statistical report was sent to CONRAD in June 2006.
- The CTR FCO #2295 was closed on June 30, 2006.

Findings and Outcomes:
- In preliminary results shared via an abstract at Microbicides 2006, genital irritation was observed. Discontinuations for product-related reasons, symptoms/signs of urogenital irritation including colposcopic findings, and changes in microflora and vaginal pH were presented at the Microbicides meeting. The higher concentrations of lime juice were associated with adverse safety events.

Funding Source(s):		USAID - US Agency for International Development/Microbicides; USAID - US Agency for International Development/Core		**FCO Approved:** **2295** **132110**	Aug 2004 Jun 2006
Total Approved Budget:	**2295**	$	162,695	**Projected End Date:**	Dec 2006
	132110	$	35,396		
		$	198,091		

Worldwide: Site Development for Microbicide Studies (previously FCO 2267)

Technical Monitor: TMassey

Status: Complete
Group: CRD

Objective(s): To develop future vaginal microbicide studies by identifying potential products and study sites, training selected staff and preparing sites for study implementation.

Description: This development FCO was used to investigate and develop new products, sites, and investigators in order to conduct microbicides studies. Those subprojects impacted by the work of this FCO are reported separately. This subproject is funded by USAID microbicides designated core funds.

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Activities, Accomplishments, Problems through December 31, 2005

- The preliminary approval to use Microbicide funds was given by USAID in September 2001.
- FHI researchers met with a Nigerian doctor on academic leave at the University of Texas (UT), Galveston Branch in November 2001.
- FHI researchers identified and visited potential microbicide sites and investigators in India in December 2001.
- FHI researchers attended the International AIDS Meeting in Mumbai to meet with potential investigators in December 2001.
- A proposal was submitted to the JWG to conduct a Phase I Praneem Polyherbal Tablet study in December 2001 (see FCO 2704).
- MipHil was acquired from Columbia Labs and sent to Dr. Doncel's laboratory at UT for testing as a potential microbicide candidate.
- Sites in Ghana, Mali, and Cameroon were visited and evaluated as microbicide trial sites in January and February 2002.
- An internet connection issue for Cameroon was resolved and an FHI/Nairobi IT staff member traveled to Cameroon to assess availability of obtaining high speed internet connection.
- FHI staff attended the Microbicide 2002 Meeting in Antwerp, May 2002.
- FHI researchers visited Lagos and Ibadan, Nigeria, to evaluate these cities as microbicide trial sites in June 2002.
- FHI researchers visited Accra and Kumasi, Ghana, to work with local investigators to conduct pre-study activities. Subsequently, Research International helped prepare the sites for an upcoming study.
- FHI researchers had contracted Research International, a local NGO in Ghana, to conduct future pre-study activities.
- An FHI researcher visited Lagos and Ibadan, Nigeria, in November 2002, to finalize pre-study issues and work with proposed investigators.
- E Raymond and D Wiener attended the "Assessing Inflammation and Epithelial Integrity in Vaginal Product Research" workshop, sponsored by CONRAD and WHO, and held in the Dominican Republic in August 2003.
- No activity took place under this subproject during this timeframe.
- The FCO and the subproject were subsequently closed at the end of September 2005.

Findings and Outcomes:

- Over the life of this subproject, FHI staff conducted site assessment visits at sites in India, Ghana, Mali, Cameroon, and Nigeria. The information gathered in these visits will aid in the planning for future studies.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2001
Total Approved Budget:	Annually Approved	**Projected End Date:**	Sep 2005

India: Indo-US Collaborations on STIs and RTIs (FCO 2702 and previously 7702)

Technical Monitor: LDorflinger
Collaborating Agency(s): NICHD
Status: Complete
Group: CRD

Objective(s): 1) To coordinate attendance of FHI and other US-based experts at the Indo-US Joint Working Group Workshops on Sexually Transmitted Diseases and Reproductive Tract Infections; and 2) to identify and develop potential Indo-US collaborations and to jointly develop research subprojects on STD prevalence and microbicides in collaboration with the Indo-US Joint Working Group.

Note: In the June 2001 report, the research objective was revised to clarify that this subproject would cover the identification and development of worthy research ideas but not necessarily the full costs of implementation. India side costs for collaborations would be covered with local funds, once approved through the Indo-US Joint Working Group.

Description: This subproject involved the coordination of FHI and other US-based expert attendance at Indo-US Joint Working Group Workshops, as well as the development and partial funding of Indo-US collaborative research subprojects. The Indo-US Joint Working Group (JWG) Workshop on Sexually Transmitted Diseases and Reproductive Tract Infections was held in New Delhi, November 8-10, 2000. The workshop's goals were: to provide state-of-the-art presentations with regard to antecedents, prevention, diagnosis, and treatment of STDs and RTIs; to develop a joint research agenda; and to provide an opportunity for the identification and development of potential Indo-US collaborations. A second workshop, entitled "The Role of Reproductive Tract Health in Prevention and Treatment of Sexually Transmitted Diseases" was to be supported through this interagency agreement, although FHI interagency funds were ultimately not used for this activity. Developmental work on activities related to STD prevalence and/or microbicides has also been conducted under this subproject. The subproject was supported by an Interagency Agreement, # 0179F, between NIH and USAID.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI coordinated the attendance by two FHI staff, eight other US scientists and approximately 50 Indian scientists at the Indo-US Joint Working Group (JWG) Workshop on Sexually Transmitted Diseases and Reproductive Tract Infections in New Delhi, November 8-10, 2000.
- Following the meeting, potential research sites were visited to determine if collaborators could be identified. A proposal was submitted to the JWG for funding of a Phase I study of Praneem Polyherbal Gel and tablets. The proposal was reviewed in April 2001 by the JWG. It was also reviewed and further discussed at the October 2002 meeting of the JWG.
- FHI staff continued working with Dr. Sarala Gopalan, Postgraduate Medical Institute for Medical Education and Research in Chandigarh, India and Dr. G. P. Talwar, the Talwar Research Foundation in New Delhi, India to further develop the study protocol and gain its approval by the appropriate review bodies. While a separate FCO (#2704) was established to track costs, it was closed in September 2002.
- Due to given competing priorities of FHI staff, and the continued uncertainty of funding through JWG, further work on the Praneem clinical trial was stopped.
- Support was provided for the travel of Dr. Neerja Bhatla, from the All India Institute of Medical Sciences, to Johns Hopkins University to work with Dr. Keerti Shah to revise a proposal made to the JWG in April 2001. This proposal was subsequently funded.
- A proposal was submitted to the JWG to support activities to strengthen select clinical trial sites in India to conduct high-quality research in accordance with international regulatory and

ethical standards. Included in this activity was an assessment visit followed by a workshop. A new FCO was established (3702) in October 2002, titled Institutional Support for Clinical Trial Sites in India. Refer to that subproject report for more detailed information.

- FHI passed funds to KRA Corporation to support the Indo-US Joint Working Group on Contraception and Reproductive Health Research that took place in Rockville, Maryland on August 21-23, 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI programmed the balance of funds under the Interagency Agreement to support the behavioral research of Betsy Tolley in India that is associated with clinical trials of various microbicides. These funds will be expended before August 2006. Refer to EIS reports on FCOs 136100 and 12018.

Findings and Outcomes:

- Several proposals that were conceptualized during the November 2000 workshop on STDs were submitted to the April 2001 JWG. This mechanism demonstrated the potential to generate new ideas for collaborative research subprojects. Several of these subprojects have been funded by the JWG, including the one of Dr. Bhatla and Dr. Shah which was discussed above.
- A proposal to strengthen select clinic sites in India was developed under this subproject. Once approved, a separate subproject was established, and funds were to cover the costs channeled directly from 2702 to 3702 associated with this training.

Funding Source(s):		USAID - US Agency for International Development/OYB	**FCO Approved:**	**7702**	Sep 2000
				2702	Oct 2001
Total Approved Budget:	**7702**	$ 72,708	**Projected End Date:**		Aug 2006
	2702	$ 78,433			
		$ 151,141			

Nigeria: Savvy Phase III RCT (FCO 2277/132104)

Technical Monitor: PFeldblum
Collaborating Agency(s): Biosyn, Inc.
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate

Objective(s): To assess the effectiveness of Savvy vaginal gel in preventing HIV among Nigerian women at high risk.

Description: This will be a Phase III placebo-controlled, randomized, triple-masked study. A total of 2,142 uninfected women, aged 18-35 at high risk for acquiring HIV, will be recruited over 12 months at study sites in Ibadan and Lagos, Nigeria. Women who consent to be in this study will be randomized into either a condom/Savvy or condom/placebo group and will be followed for 12 months. After completion of the study, incidence rates of HIV-1 and HIV-2 infection will be compared between the two groups.

This subproject is supported by USAID microbicide funding. Biosyn, Inc., the maker of Savvy, will supply the Savvy and placebo gels for the study.

NOTE: After negotiations with the USFDA and deciding on a final study design, USAID requested 12 months of follow-up time for each study participant and to drop gonorrhea and chlamydia as secondary endpoints. FHI amended the protocol to reflect the new study design and obtained all necessary approvals.

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Activities, Accomplishments, Problems through December 31, 2005

- Preliminary approval was granted by USAID for the use of Microbicide funds in September 2002.
- The protocol was approved by PHSC in November 2002.
- The protocol was approved by both local IRBs by May 2003.
- In May 2003, investigators, in-country monitors, and site coordinators attended a Good Clinical Practices training by Ruth Ann Nylen (The RAN Institute) in Accra, Ghana.
- The pre-study Data Monitoring Committee met at FHI in December 2003.
- The investigators from Nigeria and staff from FHI attended the London Microbicides Conference in March 2004.
- Core study training for both sites was conducted in May 2004.
- The protocol, the statistical analysis plan, and the report on OraQuick accuracy were submitted to the FDA in August 2004, and site initiation training was conducted.
- The first participant was screened in October 2004; the first participant was enrolled in November 2004 and follow-up began in December 2004.
- Revised subagreement budgets were executed by FHI and the sites. The overall FHI budget was increased by approximately 5.3% due to additions to the subagreements.
- An agreement was obtained so that study participants who become HIV-positive during the study will be referred to the local PEPFAR programs at both NIMR and UCH.
- The annual safety report was completed by FHI and submitted to Biosyn in December 2004.
- FHI data management staff developed and made available the web-based DMNet tool for determining study progress.
- An FHI audit by RAQA staff was done in February 2005.
- A member of the FHI PHSC visited the Lagos study site in June 2005.
- Quarterly checks of adverse event data commenced on frozen data sets.
- Subagreements were modified for the two NGOs who provided the Participant Advocates and In-country Monitor for the study.
- Three shipments of USAID condoms were made.
- The study protocol, consent forms, and recruitment scripts were modified. A supplemental consent form that describes additional procedures at the 6-month and 12-month visits was written and approved (ELISA testing at the final visit, and possible PCR testing).
- Five FHI monitoring visits have been made to the sites as of June 2006.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- PCR testing for HIV RNA has commenced for certain dried blood spot specimens at the University of North Carolina.
- The first interim analysis took place and a second DMC meeting took place when approximately 16 HIV events occurred in April 2006. The DMC recommended that the trial continue as planned.
- Study staff attended the 2006 Microbicide Conference in Capetown, South Africa in April and made two poster presentations and one oral presentation.
- Enrollment was completed in June 2006.

Funding Source(s): USAID - US Agency for **FCO Approved:** **2277** Aug 2002

		International Development/Core	**132104**	Jul 2005
Total Approved Budget: 2277 132104	$	7,063,771 In Approval	**Projected End Date:**	Oct 2007

Ghana: Savvy® Phase III RCT (FCO 2278/132105)

Technical Monitor: LPeterson
Collaborating Agency(s): Biosyn, Inc.

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate

Objective(s): To assess the effectiveness of Savvy vaginal gel in preventing HIV among Ghanaian women at high risk.

Description: This study was designed as a Phase III placebo-controlled, randomized, triple-masked study. A total of 2,142 uninfected women, aged 18-35 at high risk for acquiring HIV, were recruited over 15 months at study sites in Accra and Kumasi, Ghana. Women who consented to be in this study were randomized into either a condom/Savvy or condom/placebo group. The planned follow-up period was 12 months. After completion of the study, incidence rates of HIV infection were to be compared between the two groups.

This subproject is supported by USAID-designated microbicides funds. Biosyn, Inc. is the maker of Savvy and supplied the Savvy and placebo gels for the study.

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Activities, Accomplishments, Problems through December 31, 2005

- Preliminary approval was granted by USAID in September 2002.
- In November 2002, the protocol was approved by PHSC.
- Sites were visited in November 2002 for site preparation.
- Subagreements were negotiated with Komfo Anokye Teaching Hospital (KATH) and Noguchi Memorial Institute for Medical Research (NMIMR).
- In May 2003, site investigators and coordinators attended a Good Clinical Practices training by Ruth Ann Nylen (The RAN Institute) in Accra; in-country monitors also attended a monitoring training at the same time.
- A subagreement was negotiated with Virtual Access (VA) to hire the independent in-country monitor as well as the participant advocates for the study.
- An amended protocol was approved by the PHSC in August 2003, by KATH in October 2003, and by NMIMR in November 2003.
- Subagreements were executed with KATH, NMIMR, and VA in November 2003.
- Site training took place in January and February 2004.
- Clinical supplies were shipped to the sites in February 2004, and enrollment began in March 2004.
- Site refresher trainings took place in March, September, and October 2004.
- Site monitoring visits took place in May, July, and November 2004.

- A contract between FHI and Focus Technologies for in vitro testing of study gel was executed in June 2004, and results were available in August 2004.
- The Noguchi and KATH IRBs granted annual approvals in October 2004. PHSC granted annual approval in November 2004.
- Enrollment ended in June 2005.
- In June and September 2005, a DMC meetings were held to review interim data. The DMC approved study continuation at both meetings.
- The Noguchi IRB granted annual approvals in September 2005, and the KATH IBR granted annual approval in October 2005.
- Site monitoring visits occurred in February, Jane , and October 2005.
- The PHSC granted annual approval in November 2005.
- The DMC met again in November 2005 to review the study data to date and concluded that the study would be unable to evaluate the effectiveness of the product due to low incidence in the study population. Based on the DMC recommendation, a joint decision between FHI and Cellery Pharmaceutical Inc. was made to stop the study.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Participants were seen for a final follow-up visit by mid-February 2006.
- The close-out monitoring visit was conducted in February-March 2006.
- The data were cleaned in March 2006, and a database lock was completed in April 2006.
- The analysis was completed in May 2006.
- The team continued work on the final report through June 2006.

Findings and Outcomes:

- Although we could not assess effectiveness of SAVVY in this study, no safety concerns emerged from this study.
-
- Complex design and operational issues (such as lower than expected HIV incidence rates, high pregnancy rates, and low product adherence) have emerged from the SAVVY trials that exceed the traditional clinical trial challenges of recruiting participants and maintaining protocol adherence. They also are relevant for other HIV prevention technologies

Funding Source(s):		USAID – US Agency for International Development/Core	**FCO Approved: 2278**	Aug 2002
			132105	Jul 2005
Total Approved Budget: 2278	$	6,767,839	**Projected End Date:**	Oct 2006
132105		In Approval		

South Africa: Microbicides: Carraguard Phase III Trial Interim Analysis for DSMB (FCO 139100)

Technical Monitor: MChen
Collaborating Agency(s): Population Council
Status: Ongoing
Group: BIOS

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate

Objective(s): 1) To provide an independent statistician for the DSMB assigned to the Population Council's Carraguard Phase III Study. This work includes assisting in the development of an SOP, attending DSMB meetings, and preparing and distributing closed session interim analysis reports. 2) To provide assistance with the development of the final statistical analysis plan (SAP) as of January 2006.

Description: An independent statistician will assist in the development of an SOP, attend DSMB meetings (either in person or by teleconference), and prepare and distribute closed session interim analysis reports. In addition, FHI's Director of Biostatistics will provide technical leadership by assisting the Population Council with the development of their final statistical analysis plan (SAP) which includes details of the planned interim effectiveness analysis. (This component of the subproject was added at the Population Council's request.) FHI will also provide input on tables, listings and graphics shells being developed for the final report.

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Activities, Accomplishments, Problems through December 31, 2005

- A closed session report was generated for the first interim review of the Carraguard study following the SOP previously developed. The interim report was distributed to the DSMB members, and the independent statistician traveled to Cape Town, South Africa for the meeting, held in April 2006.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI has reviewed the Population Council's draft Statistical Analysis Plan (SAP), the case report forms, the protocol and protocol amendments and discussed issues affecting the plan with Population Council staff. In collaboration with Pharmalink staff (who are being paid directly by the Population Council), FHI delivered a substantially revised draft SAP to Pharmalink in February 2006, which was finalized in June 2006. FHI assisted the Population Council as needed in responding to FDA's questions regarding the analysis plan.
- Two more interim reviews for the study occurred for which the independent statistician generated the reports. These meetings occurred by teleconference instead of face to face meetings.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jun 2005
Total Approved Budget:	$ 40,000	**Projected End Date:**	Jun 2007

Nigeria: Randomized Controlled Trial of Cellulose Sulfate (CS) Gel and HIV in Nigeria (FCO 2266/132100)

Technical Monitor: VHalpern
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate

Objective(s): 1) To determine the effectiveness of CS gel in preventing male-to-female vaginal transmission of HIV infection among women at high risk; and 2) to determine the effectiveness of CS gel in preventing male-to-female transmission of gonorrhea and chlamydial infection among women at high risk.

NOTE: A second objective was added in 2003 in order to more accurately reflect the protocol objectives.

Description: Given the continuing HIV epidemic, the search for an effective vaginal microbicide remains urgent. This is especially true in sub-Saharan Africa which bears a disproportionate burden of HIV/AIDS cases. Cellulose sulfate (CS) gel is a promising microbicide candidate. CONRAD (maker of CS gel) is the sponsor of this study and will supply the study product for this Phase III study.

This is a randomized controlled trial of 2,160 women, aged 18-35 at high risk for HIV, who will be followed for one year of study participation. Half the women will use CS gel and half will use a placebo gel. A combined incidence rate of HIV-1 and HIV-2 infection will be compared between the two groups to evaluate the effectiveness of CS gel. Also, incidence rates of gonorrhea and chlamydial infection will be similarly compared. Results from this study may help women worldwide, should the gel prove to be an effective HIV-prevention method. All women who consent to be in the study will be counseled on condom use.

This subproject is supported by USAID funds earmarked for microbicide research.

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Activities, Accomplishments, Problems through December 31, 2005

- USAID granted preliminary approval for this subproject in September 2001.
- In June 2003, visits were made to Nigeria to meet with potential investigators and to visit potential sites in Lagos and Port Harcourt.
- The protocol was approved by the PHSC in August 2003.
- The National Agency for Food and Drug Control (NAFDAC) approved the protocol in December 2003.
- FHI attended an FDA meeting in April 2004, and the protocol and forms were subsequently revised.
- FHI staff visited both study sites in May and June 2004 to continue discussions on implementation.
- Training for laboratory staff was held in South Africa in May and December 2004; and for study staff in August and October 2004.
- The first DMC meeting was held in September 2004.

- The Institute for Tropical Medicine, the study's quality control group, conducted a lab test procedures training in October 2004 and retraining in January 2005.
- Screening began at both sites in late November 2004.
- The Lagos site was monitored in February 2005, June 2005, September 2005. The Port Harcourt site was monitored in February 2005 and June 2005.
- FHI's RAQA conducted a site audit in March 2005 and a follow-up site audit in August 2005.
- The protocol and informed consents were amended to add PCR testing for HIV at the final visit for all participants in May 2005.
- Re-training in the original study procedures and training for revised procedures was conducted at both sites in June 2005.
- Literacy documentation guidelines and a literacy checklist were implemented in June 2005 in response to IC issues noted during the first monitoring visit and the RAQA audit.
- Literacy documentation guidelines and a literacy checklist were implemented in June 2005 in response to IC issues noted during the first monitoring visit and the RAQA audit.
- A new protocol and informed consent documents were approved by the PHSC and local IRBs and were implemented at both sites by July 2005.
- Re-training by ITM staff on SDA testing was held at the Port Harcourt site in December 2005.
- Six abstracts were submitted to the 2006 Microbicide Conference in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Both sites were monitored in January 2006.
- ITM staff held retraining for the Lagos site in January 2006.
- Plans for providing contraceptive referrals and providing family planning information to study participants were formalized in January 2006. A one-day training, "Update on Contraceptive Technology", was conducted by the local Planned Parenthood affiliate; two nurses and two MDs were trained at each site.
- Based on the analysis of STI/HIV prevalence and incidence rates, the recruitment strategies were modified as follows in order to increase the HIV incidence rate: the Ikeja clinic in Lagos was closed for recruitment in January of 2006; the enrollment was significantly slowed down in Port Harcourt during February-April 2006; and all efforts were concentrated on identifying new more appropriate study populations.
- Remote Quality Assurance of ELISA and Western Blot results was conducted by RA/QA in March 2006.
- Three FHI staff and five site staff attended the Microbicides 2006 Conference in April 2006 (under FCO 132100).
- At the May 2006 quarterly data freeze, HIV incidence was still lower than expected but there was a trend towards increase in both the HIV prevalence and incidence in Port Harcourt; the incidence in Lagos was still high. However, the pregnancy rate and potential lost to follow-up rate were higher than expected in Lagos.
- A monitoring visit was conducted at the Lagos site in June 2006.
- Travel bans to Port Harcourt have been on-going due to political unrest in the area. FHI remotely monitored the Port Harcourt site using copies of source documents in June 2006.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved: 2266**	Sep 2001
			132100	Jul 2005
Total Approved Budget: 2266	$	8,323,009	**Projected End Date:**	Sep 2007
132100	$	2,723,000		
	$	11,046,009		

South Africa: RCT of Tenofovir Gel in South Africa (FCO 132108)

Technical Monitor: ATroxler
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate

Objective(s): To assess the safety and effectiveness of candidate vaginal microbicide 1% tenofovir gel, relative to a placebo gel in preventing sexually transmitted HIV infection. The primary outcome of interest is seroconversion. Secondary objectives include: incidence rate of deep epithelial disruption, assessing the impact of either product on viral load for women who become infected during the trial, assessing tenofovir resistance among HIV seroconverters, assessing effectiveness in preventing HSV-2 transmission, verifying participant reported recall of last sexual encounter with biomarkers of semen, verifying participant recall of product use with biomarkers of product presence, and assessing user acceptability.

Description: This trial will complement the new study proposed in this workplan which compares oral tenofovir with tenofovir gel. The study will be conducted in South Africa by CAPRISA with Dr. Quarraishia Karim as the Principal Investigator. Patients will be recruited from the two areas: the Vulindlela clinic population, and in Durban among a population attending the Prince Cyril Zulu Communicable Disease Centre (eThekwini Clinic) and the Umbilo Clinic located next to the CAPRISA's main office. Vulindlela has a very high prevalence of HIV, with almost 43% of women in antenatal surveys HIV positive while the prevalence of HIV among those attending the Prince Cyril Zulu CDC is over 60%.
As currently planned, this study will be a Phase IIb, two-armed, double-blinded, randomized, controlled trial comparing 1% Tenofovir gel with the universal HEC placebo gel. Nine hundred and eighty (980) HIV negative sexually active women (18-40 years) at high risk will be recruited. A DSMB will review the study at strategically chosen time points in enrollment to determine whether the study should continue, be modified, or be discontinued. FHI will provide collaborative oversight and coordination to the trial, provide data management and analysis consulting services, provide monitoring and quality assurance audits, oversee the management of the IND for the study, and collaborate on behavioral research and community preparation activities. CONRAD will provide Tenofovir gel product for the trial.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A Project Leader and Project Manager were selected.
- A Data Management assessment visit was completed in April 2006.
- A draft protocol was provided by the site.

Funding Source(s):	USAID - US Agency for International Development/Microbicides	**FCO Approved:**	Feb 2006
Total Approved Budget:	$ 92,001	**Projected End Date:**	Apr 2010

South Africa: Safety and Feasibility of the Diaphragm Used with ACIDFORM (FCO 2276/112103)

Technical Monitor: SWevill
Collaborating Agency(s): CONRAD

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate
Two new delivery systems/methods of administration for topical microbicides evaluated. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate

Objective(s): To provide statistical, data management, and clinical monitoring support for a CONRAD study. The study's objectives are: 1) to assess the effect of a diaphragm used with ACIDFORM (vs. one used with KY Jelly) on symptoms and signs of irritation of the external genitalia, vagina, and cervix; 2) to evaluate the willingness of women to use the diaphragm with a gel prior to each vaginal sexual act for a period of 6 months; and 3) to compare the differences in vaginal health following 6 months use of a diaphragm with ACIDFORM vs. one used with KY Jelly.

Description: ACIDFORM gel was developed with the principle that an acid-buffering vaginal formulation that maintains the vaginal pH below 5.0 when the ejaculate is introduced in the vagina or when a vaginal infection is present would be both an ideal contraceptive and anti-microbial agent. Based on pre-clinical and clinical data, ACIDFORM gel appears to be a promising candidate spermicide and microbicide, with an excellent safety profile justifying further development and evaluation.

This placebo-controlled, randomized, triple-masked study included 120 sexually active women at low risk for HIV infection. Participants were instructed to insert a diaphragm and apply either ACIDFORM or KY Jelly prior to having vaginal intercourse for a period of 6 months. They were instructed to leave the diaphragm in the vagina for a minimum of 8 and a maximum of 24 hours after intercourse. If they had multiple sexual acts during this period, they were instructed to apply a new dose of vaginal gel with each act.

Following use of the assigned product, signs and symptoms of irritation to external genitalia, vagina, and cervix were assessed through a review of disruption of the epithelium and blood vessels as seen on colposcopy. Differences in vaginal health will be assessed using results of wet mounts, pH, gram stains and cervical-vaginal lavages for cytokines.

FHI is providing biostatistical, data management, and monitoring support to this study. Initially, this subproject was supported by USAID funds designated for microbicide development. In July 2005, $28,600 of CTR core funds were added to this microbicides activity to facilitate subproject continuation prior to the initiation of CRTU fund disbursement. In September 2005, money to complete the study was provided via additional USAID population funds. In addition, funding for analysis of behavioral data is being provided under FCO 116101.

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Activities, Accomplishments, Problems through December 31, 2005

- The subproject was approved by USAID in August 2002.
- A site visit was completed in August 2002 to set up the behavioral component of the study.
- The data management section for the protocol was written by FHI and provided to CONRAD in November 2002.
- The protocol was approved in March 2003.
- In December 2003, CRFs were approved, and randomization was completed.
- In January 2004, the site staff were trained. Study-specific training included the behavioral component, as well as training on Good Clinical Practice and Research Ethics.
- Final local IRB approval was obtained in April 2004, and enrollment began.
- The error specifications and programming were implemented in May 2004.
- The monitoring plan was approved in June 2004, the data management plan was finalized in August and the data analysis plan was finalized in October.
- A monitoring visit was conducted in December 2004. During this visit, the team analyzed recruitment strategies and concluded that three more months of recruitment would be needed.
- In early December 2004, CONRAD suspended enrollment pending annual IRB approval of the study, as well as, approval of a protocol amendment and revised informed consent form (all of which were submitted by CONRAD to their IRB for review in October 2004). Enrollment commenced in late December 2004.
- In April 2005, the monitoring plan was revised to increase monitoring visits from every three months to every six months.
- An interim monitoring visit was conducted in August 2005.
- A separate subproject (FCO 116101) was established in August 2005 for analysis of the behavioral data for this study.
- Participant follow-up ended in late November 2005 with the exception of three women whom the site staff continued trying to contact. These women were presumed lost to follow-up. (The site staff will keep these files open until early January 2006.)

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The site closed their study files for the three remaining women, considering them lost to follow-up and documenting them as such.
- The site sent frozen cytokine samples to Belgium for analysis in January 2006. The results of these samples were to be returned to the site in late February; however, due to a lab delay, the results were sent to the site in late April. The site staff then transcribed the results onto the participant CRFs.
- The final closeout visit was done by the In-country monitor in May 2006.
- All CRFs, completed with cytokine data, and other study closeout documentation were received at FHI in June 2006.
- The study table shells were developed.
- All data were entered into the ClinTrial database, and all queries were resolved.
- The FCO was closed on August 31, 2006.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved:**	**2276**	Aug 2002
				112103	Aug 2005
Total Approved Budget:	**2276**	$ 329,186	**Projected End Date:**		Dec 2006
	112103	$ 198,852			
		$ 528,038			

South Africa: Acidform Behavioral Data Analysis (FCO 116101)

Technical Monitor: GGuest

Status: Ongoing
Group: BASS

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Acceptability of at least three different formulations or microbicide delivery systems assessed in at least three regions

Objective(s): To analyze and synthesize qualitative and quantitative data to understand acceptability of the diaphragm with Acidform gel. Specifically, the behavioral analysis plan aims to: 1) determine if subjective experience is related to reported use of the product; 2) identify predictors of positive experiences with, and/or use of, the method; 3) map experience with, and use of, the product over the course of the trial; 4) identify co-variates of product experience and use over the course of the trial; and 5) identify problems associated with correct product usage.

Description: This subproject entails data analysis and write-up of behavioral data collected during the CONRAD/FHI study (FCO 112103), "Safety and Feasibility Study of the Diaphragm Used with ACIDFORM Gel or KY Jelly". The behavioral analysis plan supplements the feasibility component of the existing Statistical Analysis Plan that was developed for the clinical trial by CRD and BIOS.
While various inferential and descriptive statistical techniques will be used to test hypotheses, Growth Curve Analysis (GCA) will be the primary method used to assess changes in acceptability by participants over time, and the relationship of these changes to both time-invariant variables (e.g., education, age) and time-varying variables (e.g., frequency of sex in past 7 days).
Qualitative data will be strategically employed to support all of the quantitative analysis. Data from open ended questions will provide insight and explanation into trends observed from the quantitative analysis.

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Activities, Accomplishments, Problems through December 31, 2005

- A data analysis plan was written and reviewed by the clinical trial PI, local investigators, and BIOS by November 2005.
- Quantitative data entry tools and templates were developed at FHI and sent to Progressus to use for data entry in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Guest traveled to Johannesburg in February 2006 to collaborate with the qualitative data analysis team at Progressus.
- Data analysis was conducted at FHI on parts of the dataset.
- Some study findings were written-up and disseminated. A poster was presented at the International Microbicides Conference in Cape Town in April 2006, and a manuscript was submitted to JAIDS in June 2006.

Findings and Outcomes:

- Women clustered into three psychographic groups that differed with respect to age, stability of relationships, HIV risk, and frequency of sex.
- In general, women evaluated the method gel and diaphragm combination favorably. In all groups, positive evaluation of the method increased after the first month of use, although evaluative trajectories varied somewhat between the three psychographic groups identified.

- Adherence to the gel and diaphragm was generally good, although it peaked at month 3 in all groups, and varied between the three psychographic groups identified. Older women in more stable relationships used the gel more frequently and consistently.
- Frequency of sex increased significantly among participants after enrollment, primarily due to perceived protection from HIV and greater sexual pleasure afforded by the gel. Male condom use was high overall, but increased significantly from enrollment. Data indicate this is due to increased partner involvement, participants' commitment to the trial, increased negotiating power afforded by study participation, and provision of condoms perceived to be of high quality.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Aug 2005
Total Approved Budget:	$ 198,852	**Projected End Date:**	Oct 2006

USA: Phase I Study of the BufferGel Duet's Functional Performance, Safety and Acceptability (FCO 2292/132102)

Technical Monitor: GPittman
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate

Objective(s): To provide statistical and data management support to a CONRAD study designed to assess the function, safety and acceptability of the BufferGel Duet, as well as the effectiveness on vaginal pH.

Description: The BufferGel Duet is a single-use disposable contraceptive intravaginal device made of clear polyurethane and preloaded on both its cervical and vaginal sides with BufferGel, a nondetergent spermicidal microbicide. The focus of this clinical study was on the functional performance of the device (ease of insertion and removal, correctness of position after insertion, and frequency of dislodgments), but safety, effect on vaginal pH and acceptability were also assessed. A total of 30 couples, healthy and not at risk for pregnancy, were enrolled at two sites and used the device for one week.

NOTE: FHI provided data management and statistical analysis support to this study, funded by USAID monies designated for microbicide development.

NOTE: The name of the device was changed to the BufferGel Duet from the BufferGel Device in late 2004. The subproject title was revised as a result.

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Activities, Accomplishments, Problems through December 31, 2005

- An FCO for this subproject was established in August 2004.
- The protocol was approved in September 2004.

- Study development was delayed due to product availability.
- Case Report Forms were drafted by CONRAD and sent to FHI in December 2004.
- The CRFs were finalized in January 2005.
- The Investigators Meeting was held in February 2005.
- Enrollment began in May 2005.
- The data management plan was finalized in July 2005.
- Data entry screens were developed, and the ClinTrial data entry system completed in August 2005.
- A new FCO was established using microbicide funds allocated under the CRTU in August 2005 (FCO 132102).
- Enrollment ended, the study sites were closed, and all data were received in-house in November 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Data entry and querying were completed.
- The analysis plan was finalized and approved.
- Final data freeze and tables needed for CONRAD's presentation at the 2006 Microbicide Conference were completed in March 2006.
- The final statistical report was sent to CONRAD in May 2006.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved: 2292**	Aug 2004
			132102	Aug 2005
Total Approved Budget: 2292	$	130,912	**Projected End Date:**	Sep 2006
132102		N/A		

India: Sustained Acceptability of Vaginal Microbicides: Male and Female Perspectives (FCO 136100/116105 and previously 9386)

Technical Monitor: BTolley

Status: Ongoing
Group: BASS

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested
To obtain information needed to help interpret clinical trial results and to improve the design and implementation of future trials, social and behavioral studies will be conducted on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies

Objective(s): 1) To identify and describe factors that enable individuals and couples to use microbicides consistently and long-term; and 2) to account for the effects of clinical trial and acceptability research participation on microbicide use including: motivations for joining the trial; the importance of counseling and support provided by clinical trial staff in maintaining product use; and the importance of interactions with acceptability research staff in maintaining product use.

Description: The Sustained Acceptability study integrates qualitative and quantitative methods in a longitudinal study of microbicide acceptability in Pune, India. It does so by building on to Phase I (FCO 433) and Phase II microbicide clinical trials research funded by NIAID and implemented under the auspices of the HIV Prevention Trials Network (HPTN). A pilot study, conducted during the Phase I clinical trial, included repeated in-depth interviews with high and low-risk individuals and couples on key concepts believed to influence risk-reduction behaviors including: HIV risk perception, self efficacy, couple harmony, and sexual communication. Based on the qualitative data, approximately 130 items were drafted to represent key concepts. The items were then administered to 300 women and 150 male partners and factor analyzed to produce draft psychometric scales which will be used in a longitudinal assessment of acceptability.
A total of 100 women will be enrolled in the HPTN Phase II parent study and followed for 6 months. These women and their primary partners will be recruited into the parallel acceptability study. Participants will provide two sets of data: core acceptability data developed for the clinical trial and enhanced acceptability data. The enhanced questionnaires will measure individual and couple scores on key psychosocial factors believed to mediate microbicide or condom use, as well as motivations for clinical trial participation. A second cohort of 100 women who were screened but found ineligible to participate in the HPTN parent study, along with their primary partners, will also be recruited, but administered the enhanced questionnaire only. In addition, clinical trial providers and a small sample of women and willing partners will also be interviewed in-depth, using a more flexible and open format.
Note: This study has two PHSC numbers: 9781 and 9481.

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Activities, Accomplishments, Problems through December 31, 2005

- Preliminary approval to develop the subproject was obtained from USAID/W in November 2001.
- The pilot study protocol was approved by NARI's IRB in India on June 28, 2002 and FHI's PHSC in October 2002.
- A protocol for the prospective study was approved by the PHSC in November 2003.
- The pilot study protocol was approved by the Health Ministry Steering Committee (HMSC) in May 2003.
- The TM conducted a six-day training workshop in October 2003, attended by interviewer candidates for the research study.
- Qualitative data collection for the pilot study began on October 15, 2003 and was completed in February 2004. A total of 106 transcripts were analyzed relating to repeated in-depth interviews with 30 women, 15 husbands and 9 key informants.
- A data analysis workshop was conducted in February 2004 to identify scale items and draft a questionnaire.
- The TM and a senior analyst visited NARI in June 2004 to train the field study staff on qualitative software, and to finalize logistics for implementation of the scale survey.
- In February-March 2005, a questionnaire was developed and administered to a total of 456 individuals (305 women and 151 husbands) to test the reliability and validity of the scales.
- The quantitative data were factor analyzed in April 2005, and a final questionnaire was drafted for use in the prospective study.
- NARI withdrew from the HPTN 035 Phase IIb study, due to problems with retention and lack of sero-incidence in their lead-in preparedness trial (HPTN 034). However the organization will be implementing a Phase II clinical trial of another microbicide gel product, Tenofovir (HPTN 059).
- The prospective protocol was revised and approved in December 2004. FHI requested and received approval from USAID to shift the prospective acceptability research onto HPTN 059.
- NARI's pilot study subagreement was revised and extended to include implementation of behavioral and social science research to prepare for implementation of the HPTN 059 microbicide safety trial. The PHSC reviewed and approved these changes in July 2005.

- The pilot and prospective study subagreements were submitted to PHSC and approved for continuation in September and November 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In March 2006, the TM and analyst participated in the HPTN 059 clinical trial site initiation training, during which time they trained five acceptability staff in procedures for the prospective acceptability study.
- Findings from the pilot study were presented at the 2006 Microbicide Conference in April 2006, in Cape Town, South Africa.
- The prospective study data entry program and a data management manual were finalized in June 2006.

Findings and Outcomes:

- The qualitative phase of this study found that women will not likely consider microbicide use unless they perceive themselves to be at risk of HIV. HIV risk was most commonly associated with a partner's infidelity, easily detected according to both men and women by a lack of marital harmony. Despite this logical pathway, high-risk women in this study denied perceiving HIV risk until confronted with specific evidence in the form of a husband's positive HIV test or diagnosis of a sexually transmitted disease.
- Overall, women's perceptions of control and sexual power appeared to influence attitudes towards consistency of microbicide use. The identification of HIV risk perception, couple harmony and sexual power constructs as potential determinants of microbicide use was further confirmed by findings from the scale survey.
- Factor analysis of the draft scale items produced five scales, four of which exhibited adequate to high levels of reliability. These included scales measuring couple harmony, Perception of Partner Infidelity, AIDS Fatalism, Pervasiveness of HIV Risk, and Protection Efficacy.
- Findings were recently published in the July/August 2006 edition of "Culture, Health & Sexuality; in an article entitled "Examining the context of microbicide acceptability among married women and men in India."

Funding Source(s):			USAID - US Agency for International Development/Core	**FCO Approved: 9386**	Oct 2001
				136100	Dec 2005
Total Approved Budget: 9386		$	822,278	**Projected End Date:**	Feb 2008
136100		$	269,629		
		$	1,091,907		

USA: New Delivery Device for Vaginal Microbicides (FCO 1844/132103 and previously 2290)

Technical Monitor: DSokal

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Two new delivery systems/methods of administration for topical microbicides evaluated. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate

Objective(s): 1) To develop hand-made prototypes of a new vaginal delivery device for microbicides or other vaginal preparations; and 2) to assess acceptability of the device via focus group discussions or in-depth interviews.

Description: Current vaginal applicators are designed to deliver a prescribed amount of drug or lubricant. Though inexpensive, these applicators do not always deliver effective drug doses. Efficacious drug delivery is dependent on three factors: (1) delivery of the drug into the vagina; (2) spread of that drug throughout the vaginal vault; and (3) retention of the drug in the vagina. Consequently, efficacy and user satisfaction may be compromised by human error that results in leakage and/or inadequate coverage/spread of the drug. The proposed device was intended to employ an applicator technology that had not previously been used for vaginal microbicides, and placement, retention and leakage were intended to be minimized through the use of a non-woven material. It was believed that this device would release microbicide evenly, retain drug within the vagina for longer periods of time, and possibly allow for multiple sexual acts without re-dosing. Its unique design would possibly provide a degree of physical barrier protection as well.

Under this subproject, a new vaginal delivery device for microbicides or other vaginal preparations was to be prepared. Focus group discussions or in-depth interviews regarding prototype acceptability were planned. Meanwhile, a review of relevant patents was planned, and a patent application for the new device was to be prepared. This activity is funded with USAID funds designated for microbicide research and private funds.

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Activities, Accomplishments, Problems through December 31, 2005

- USAID approval for this activity was received in July 2004.
- A graduate student was recruited from the NC State College of Textiles to work part-time on the subproject.
- Two consultants were identified from a list provided by the national non-wovens trade association. One of these consultants was contracted to provide expertise and guide the prototype development process.
- Several non-woven prototypes were developed.
- Two working sessions were held to review the invention and the new product concept (new prototypes).
- During the second working session, a major improvement was identified for the prototype which justified a new patent. An invention disclosure document was drafted.
- CONRAD asked FHI to provide a “gauze-like” non-woven device for use in the planned Phase I safety trial of citric acid. Acceptability data from this trial will assist with further product development.

- Vaginal drug delivery devices were provided for CONRAD's Phase I safety trial of citric acid, which began in February 2005.
- A protocol and study instruments to gather qualitative data from citric acid study participants were developed.
- The patentability of the improved prototype was evaluated. Our prototype was found to be patentable. A provisional patent application was drafted for submission in August 2005 (using other funding).
- Limited information on the new prototype was shared with other microbicide research teams in an effort to find additional funding and identify other collaborators.
- During the period of January 2005 to June 2005, funding for this activity was limited, which led to several consequences: (a) qualitative research could not be conducted, thus planned focus group sessions did not occur; (b) work on the patent application proceeded at a slow pace; and (c) only very limited work was possible on testing of the new prototypes.
- Some related qualitative research, i.e., in-depth interviews, was done under FCO 2295 from July 2005 to November 2005, on devices that were prepared for CONRAD's Phase I evaluation of lime juice as a vaginal microbicide.
- A revised request for funding was submitted in December 2005 to the International Partnership for Microbicides.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A contract was finalized with the International Partnership for Microbicides. The funding was awarded to FHI in May 2006, and work began immediately on further prototype development and evaluation in preparation for acceptability testing.
- A patent application was submitted for our improved prototype in June 2006.

Findings and Outcomes:

- A unique non-woven vaginal drug delivery prototype was developed. It is believed that the device will deliver microbicides more efficiently than currently available methods. The device is inexpensive and can be manufactured and packaged for about $0.05 per unit (excluding drug).

Funding Source(s):		International Partnership for Microbicides (IPM)/Private; USAID - US Agency for International Development/Core	**FCO Approved:**	**2290**	Jun 2004
				132103	Aug 2005
				1844	May 2006
Total Approved Budget:	**2290**	$ 220,917	**Projected End Date:**		Oct 2007
	132103	$ 25,000			
	1844	$ 72,171			
		$ 318,088			

USA: Development of a Phase II Microbicide Trial Protocol (FCO 132107)

Technical Monitor: PFeldblum

Status: Canceled
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Objective(s): To devise an approach to gather preliminary evidence of microbicide effectiveness prior to initiating a costly and lengthy Phase III trial.

Description: The highest priority for microbicide research is to demonstrate that use of a specific product can safely reduce the risk of HIV acquisition among women. Until now, FHI's and other clinical development strategies for microbicides have involved going from extended Phase I safety studies directly to Phase IIb or Phase III trials with sample sizes of over 1,000 participants per treatment and follow-up for at least one year.
We proposed to assemble a multidisciplinary team to consider alternative approaches to the design and analysis of a Phase II microbicide trial. The team was to develop a sample protocol with their recommended approach; vet the proposed approach among scientists, stakeholders and regulators; identify the target population characteristics for the Phase II trial; and initiate a search for sites that would be able to successfully recruit, enroll and follow participants that required target population characteristics. The plan was to present the proposed study design to FDA and also to scientific colleagues and stakeholders at ongoing meetings (eg, Microbicide Alliance Mtg)
The goal of the Phase II trial was to efficiently a) identify a product likely to show evidence in effectiveness in a Phase III trial, or b) rule out a product unlikely to show effectiveness in a Phase III trial. Some of the ideas that will be explored for inclusion in the phase II protocol are 1) inclusion criteria to identify very high risk women (eg, using PSA testing or other assays to identify women with recent exposure to unprotected intercourse or other risk factors at enrollment; requiring an STI positive test result at screening; recruiting discordant couples; limiting the trial to young unmarried women), 2) use of innovative participant tracking tools, 3) use of Bayesian interim monitoring techniques and analysis approaches that account for biologically validated adherence measures, and 4) measuring HIV incidence during screening and run-in to validate site eligibility.

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Activities, Accomplishments, Problems through December 31, 2005

- Citations and other materials were gathered to inform protocol development.
- Preliminary discussions were held among CRD and BIOS staff.
- The FCO and the subproject were closed in March 2006.

Findings and Outcomes:

- The subproject was canceled in March 2006. Funds and labor had to be applied to other projects in CRD. Preliminary discussions on this subproject will be useful in the development of future microbicide protocols.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Dec 2005
Total Approved Budget:	N/A	**Projected End Date:**	Mar 2006

Worldwide: Independent Monitoring of CONRAD Collaborative Studies (FCO 2285/132101)

Technical Monitor: GPittman
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Five phase III pivotal trials of topical microbicides completed. Results will be submitted to the FDA, other regulatory bodies, and other interested parties, as appropriate Through Phase I trials in collaboration with CONRAD, the initial safety of three new microbicide candidates determined. Results will be submitted to the FDA, other regulatory bodies, and other interested parties as appropriate

Objective(s): To provide clinical monitoring services to CONRAD specifically for those studies funded by USAID.

Description: This subproject is funded by USAID designated microbicide funds and is intended to cover monitoring of USAID-supported CONRAD microbicide research. When monitoring services are provided in addition to statistical and/or data management support services, then monitoring costs are charged directly to the study-specific FCO.

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Activities, Accomplishments, Problems through December 31, 2005

- The original FCO for this subproject was established in October 2003.
- A closeout monitoring visit was completed in October 2003 for the study titled, "A Randomized Controlled Trial of the Diaphragm to Prevent Sexually Transmitted Infections," that was conducted in Nairobi, Kenya.
- An interim monitoring visit was completed in January 2004 for the formative portion (Phase I) of the study titled, "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners." This study was conducted in Nairobi, Kenya.
- An initiation visit was completed in May 2004 for the study titled, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate (CS) and KY Jelly." This study was conducted in Zimbabwe.
- An initiation visit was completed in September 2004, for the safety portion (Phase II) of the study "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners." This study was conducted in Nairobi, Kenya.
- An interim monitoring visit was conducted in January 2005 in Zimbabwe for the study titled, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate (CS) and KY Jelly."
- In May 2005, an interim monitoring visit was conducted in Nairobi, Kenya, for the study titled, "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners."
- An interim visit was conducted in August 2005 in Zimbabwe for the study titled, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate (CS) and KY Jelly." During this visit, the monitor worked with the site to resolve the May 2005 audit findings, as assigned by CONRAD.
- The CTR-related FCO (2285) was closed and a new FCO (132101) was opened with microbicide funding under the CRTU.
- In August 2005, a closeout visit was conducted in Nairobi, Kenya for the study titled, "Diaphragm Acceptability among Sex Workers, Their Clients, and Their Partners."
- A closeout visit was conducted in November 2005 in Zimbabwe for the study titled, "A Phase I Safety Trial of the Diaphragm Used with Sodium Cellulose Sulfate (CS) and KY Jelly."

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- There was little activity for this subproject during this time period.

Findings and Outcomes:

- As part of the ongoing FHI-CONRAD collaboration, FHI completed clinical monitoring services as agreed to by FHI and CONRAD.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved: 2285**	Oct 2003
			132101	Jul 2005
Total Approved Budget: 2285	$	164,234	**Projected End Date:**	Jun 2007
132101		In Approval		

USA: Meeting on Pregnancy in Microbicide Studies (FCO 132106/172001)

Technical Monitor: ERaymond

Status: Complete
Group: CRD

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: Innovative strategies to increase retention and reduce product interruptions in trials developed and tested

Objective(s): To convene a meeting to discuss the issue of microbicide trial participants becoming pregnant.

Description: Numerous critical issues have arisen related to pregnancies in microbicide trials, including: requirements to stop product use during pregnancy, and implications of this requirement for interpretation of results; ethical and practical issues regarding prevention of pregnancy during trials; and detection and management of pregnancies during trials.
In November 2005, FHI hosted a meeting on these issues in conjunction with the Clinical Trials Working Group meeting organized by the Alliance for Microbicide Development. A paper was presented on these topics at the 2006 Microbicide Conference held in Capetown, South Africa in April.
This subproject is co-funded using USAID microbicides and NIH funds.

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Activities, Accomplishments, Problems through December 31, 2005

- In November 2005, about 46 people attended a meeting in Chapel Hill, North Carolina, including microbicide researchers, other experts and interested people.
- A manuscript summarizing the key themes raised at that meeting was prepared and submitted to a peer reviewed journal.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A meeting of the Alliance for Microbicide Development was held in Washington, DC in January 2006.

- A manuscript summarizing the key themes raised at that meeting was prepared and submitted to a peer reviewed journal.
- A presentation summarizing the paper was made at the 2006 Microbicide Conference in Cape Town, South Africa in April 2006.

Findings and Outcomes:

- In November 2005, FHI hosted a meeting on these issues in conjunction with the Clinical Trials Working Group meeting organized by the Alliance for Microbicide Development. A paper was presented on these topics at the 2006 Microbicide Conference held in Capetown, South Africa in April.

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/OYB	**FCO Approved:**	**172001**	Sep 2005
				132106	Sep 2005
Total Approved Budget:	**172001**	$ 75,000	**Projected End Date:**		Jul 2006
	132106	$ 95,000			
		$ 170,000			

USA: Statistical Support - Microbicides (FCO 139101)

Technical Monitor: DTaylor

Status: Ongoing
Group: BIOS

USAID Intermediate Outcome: IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: Two new approaches for evaluating the safety or effectiveness of topical microbicides developed and validated. Results will be shared with other research organizations, funding agencies, and other interested parties
To obtain information needed to help interpret clinical trial results and to improve the design and implementation of future trials, social and behavioral studies will be conducted on: sexual relationships and practices, the social and cultural context for microbicides, potential for covert use, and community support and policies

Objective(s): 1) To review statistical methods needed to answer questions concerning the effectiveness of microbicides in preventing HIV/STI transmission; 2) to conduct research on such methods; and 3) to develop recommendations for study design and analysis.

Description: Randomized trials designed to evaluate the effectiveness of microbicides in preventing HIV/STI transmission pose a number of statistical challenges. These challenges include, but are not limited to: choice of an appropriate control, heretogeneity of randomized participants, interval censoring of outcomes, and competing risks due to co-infections. We also need more efficient study designs for evaluating effectiveness against HIV, other STIs and pregnancy.

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Activities, Accomplishments, Problems through December 31, 2005

- Statistical methods for estimating HIV incidence from age-specific prevalence data were reviewed and an existing worksheet for this purpose was improved by adding confidence interval calculations and taking into account mortality rates. This worksheet is being used as a tool for microbicide site selection.
- In November 2005, Douglas Taylor prepared a presentation entitled “Statistical Challenges in the Design of Efficacy Trials” which he delivered at the NIH-sponsored Sydney Microbicides Symposium “Microbicides for Prevention of HIV Transmission: Current and Future Perspectives.” (FHI staff time only; NIH funded travel and lodging costs).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Douglas Taylor gave a presentation entitled "Statistical Implications of Withholding Study Medication on the Outcome of Microbicide Trials" at the HPTN-sponsored Microbicide Safety Consensus Meeting in Bethesda, Maryland held in March 2006.
- Staff provided miscellaneous statistical consultation to USAID-funded organizations (e.g., the Population Council, PATH) and collaborators working on microbicide development.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jun 2005
Total Approved Budget:	$ 10,000	**Projected End Date:**	Jun 2009

Crosscutting themes include capacity building, support to other projects, utilization of research results, field presence, and program guidance and oversight:

- *Capacity building remains a central challenge for reproductive health research. Capable and qualified professionals are urgently needed to carry out priority research and to craft the policies and programs that expand access to services. [Likewise] The need for research sites qualified to conduct registrational-quality clinical trials is acute, particularly for priority microbicide clinical trials.*
- *FHI has a long tradition of providing support to other organizations with our well-developed capacities in biostatistics, data management, health care economics, behavioral research, behavior change communication (BCC), training, knowledge management, and scientific writing.*
- *The RtoP Initiative, launched in 2001, represents FHI's focused effort to improve the efficiency with which research leads to improvements in practice. The Initiative serves as a bridge from researchers to users of research, who may lack immediate access, skills, or inclination to focus on new findings and their implications.*

FHI CRTU Proposal, September 30, 2004, pp.36-39. Cross-Cutting Activities

CROSS-CUTTING ACTIVITIES

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

Worldwide:	CRTU Knowledge Management (FCO 113118)
Worldwide:	Implementing Best Practices Consortium (FCO 113116)
Worldwide:	CRTU Network of Champions (FCO 113113)
Worldwide:	Research to Practice Leadership (FCO 113114)
Worldwide:	USAID Best Practices Package: Development and M & E (FCO 113115/123101)
Kenya:	Evaluation of What's New & Cool for Youth Booklet (FCO 143101)
Nigeria:	Evidence-based Child Spacing Intervention Development for Northern Nigeria (FCO 143104)
Kenya:	Building Strategic Information Capacity within NASCOP (FCO 153102)
Worldwide:	Research Ethics Training Curriculum for Community Representatives (RETC-CR) (FCO 172000 and previously 1398/1600/1601/2710)
Worldwide:	BASS Technical leadership (FCO 116103)
Worldwide:	BIOS Technical Leadership (FCO 119100)
Worldwide:	CRD Technical Leadership (FCO 112120)
Worldwide:	HSR Technical Leadership (FCO 114106)
USA:	Development of Guidelines for Contraceptive Users (FCO 112110/172003 and previously 2706)

Worldwide:	Cochrane Fertility Regulation Review Group, 2005 – 2010 (FCO 112112/172002)
Worldwide:	Inter-Laboratory Trials (FCO 118104)
Worldwide:	International Students Development (FCO 118100)
Worldwide:	Technical Assistance to Field Programs (FCO 118102)
Worldwide:	Technical Leadership: Collaboration with Multi/Bi-Lateral Procurement Agencies (FCO 118101)
Worldwide:	Technical Oversight Committee (FCO 118103)
Worldwide:	Test Capability Development and Enhancement (FCO 118105)
Worldwide:	Production Surveillance, Domestic and Off-Shore, for Hormonal and Long-acting and Permanent Methods (FCO 148101)
USA:	CTR End-of-Project & CRTU Project Launch Meeting (FCO 113120)
Multiple:	Enhanced Country Program Implementation (FCO 113117)
Kenya:	Enhanced Country Program Implementation (FCO 113122)
South Africa:	Enhanced Country Program Implementation (FCO 113123/133100)
Uganda:	Enhanced Country Program (FCO 113125)
Worldwide:	CRTU Monitoring and Evaluation (FOC 119501)
Kenya:	Kenya Division of Reproductive Health Capacity Development: Follow-on Activity (FCO 143103)

Worldwide: CRTU Knowledge Management (FCO 113118)

Technical Monitor: BRobinson

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop communications and dissemination strategies for all relevant research; 2) to implement CRTU research dissemination priorities; 3) to provide technical assistance in dissemination; and 4) to maintain core infrastructures to support CRTU dissemination and issues management.

Description: This subproject maintains scientific synthesis writing capabilities, manages planning and implementation of routine/cross-cutting research dissemination/communications, ensures the transfer of CRTU results to MOU partners for dissemination, engages research stakeholders through communications outreach, and develops/implements communication strategies for potentially controversial CRTU research. In support of specific RtoP subprojects, promotes access to relevant syntheses of research information among CRTU partners in a position to influence application in service delivery, provider training and news media, especially in focus countries. This subproject includes issues management, i.e., proactive planning to prevent problems from occurring, and quick response to mitigate damage once a problem related to USAID-supported contraceptive technology research has come up. In enhanced countries where high-visibility research is conducted, it involves management of partnerships relevant to community outreach. It also supports CRTU M&E by documenting and disseminating evidence of research utilization activities specific to communication.
Activities:
Conduct scans and country-specific communications diagnoses to identify opportunities/priorities.
Write/distribute major syntheses of research for use in facilitating discussion among service delivery organizations on future research/interventions.
Develop/implement two major topical communications strategies and related materials packets on planned topic areas, as well as specific communications plans for all relevant research or products (with co-funding).
Coordinate with staff at CAs and CRTU partners to promote dissemination of findings and to provide technical assistance to USAID and researchers for small dissemination activities.
Maintain dissemination databases on: key research stakeholder contacts; news media covering RH; project-specific photos; a calendar of emerging CRTU research; and impact indicators.

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Activities, Accomplishments, Problems through December 31, 2005

- Communications materials were developed for microbicides research and for a neonatal mouse carcinogenesis study of quinacrine.
- Five press releases were distributed, including LNG-IUS use in women with diabetes, and vasectomy techniques in Asia. Media inquiries on CRTU research were handled and media relations support was provided to field projects and partners, including PATH and the Population Council.
- CRTU findings were sent to listservs and others reaching 102,378 individuals; and shared with commercial online databases including CINAHL and Gale Publishing.

- Quarterly research briefs (English and Spanish) were sent to 3,366 individuals, including 300 USAID PHN staff.
- Staff maintained 2,000 RH publications on the Web site. Such RH materials were visited 769,270 times, representing 63% of total visits (1,223,000) to the site for 7/05-12/05.
- The mailing list was updated for 4,545 records and 968 new RH records were added (co-funded with G&A).
- Staff responded to 1,075 email requests for information and 4,879 letters and address forms; and distributed 14,719 copies of various publications.
- In October 2005, FHI wrote and INFO published a Global Health Technical Brief, "Hormonal Contraception and HIV: More Research Needed; No Changes in Family Planning Practices Currently Warranted."
- Staff provided TA to PAHO on a 286-page Spanish qualitative research manual, published by PAHO in November 2005; web and editorial expertise to Kenyan DRH for their Web site on RH; and to multiple subprojects or partners with dissemination and materials development (Ghana Savvy study; cellulose sulfate study; helped PATH with Outlook issue on HIV and contraception; edited book chapter on contraceptive access; provided support to INFO on Jim Shelton's Pearls (Spanish translation and editing).
- Staff developed M&E indicators for research dissemination with HIPNET; and coordinated future publications with PATH, Pop Council, EngenderHealth, INFO Project and MSH. Staff represented FHI on the USAID Interagency Working Group on FGC, and on the Microbicides Media Communications Initiative, as well as on USAID's Engaging Men in Reproductive Health and HIV Prevention group.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI staff:
- Implemented 9 communication plans (Kenya FP Guidelines, Quinacrine, microbicides research and Microbicides 2006.
- Distributed 14 Inside FHI newsletters; 23 research/program briefs, and 10 briefs (Spanish). Wrote technical brief on using contraception to prevent mother-to-child transmission of HIV.
- Distributed 23 tailored announcements (total of 18,517). FHI distributed listserv announcements (21,107 recipients) on provider checklists.
- Responded to 1,211 information requests (60 media) and 3,782 letters.
- Mailed 35,873 copies of CRTU materials.
- PAHO published a Spanish translation of a field guide on qualitative research.
- Staff translated a module on Contraception for Couples with HIV into French.
- Staff supported printing of 9 RH synthesis articles in Medical Education Resource Africa (MERA), each of which is distributed to 12,000 health professionals in Africa.
- Staff attended a regional forum in Dar Es Salaam, and regional meeting on sexual health in Kenya and assisted the National Press Foundation to identify expert speakers for a family planning workshop for African Journalists in Nairobi in June 2006.
- FHI staff strengthened mailing lists.
- Repackaged the contraceptive continuation literature review for use by the INFO Project, and provided them: Spanish translation and editing support on Jim Shelton's Pearls; technical review of an upcoming Population Report on contraceptive continuation; and content on CBD of injectables for an upcoming Population Report.
- Participated in PATH's Microbicides Media Communications Initiative.
- Co-published a 34-page issue of Quality/Calidad/Qualite, "With Our Lives at Stake: SWAA Ghana Champions the Female Condom" (in press), providing technical and editorial review for the Pop Council.
- Provided TA to partners in South Africa and Nigeria.
- Continued work on two topical communications strategies. Coordinated communications approaches among CAs related to issues requiring special media management.

Findings and Outcomes:

- The Global Campaign for Microbicides has incorporated FHI's communications plan template into materials used by member research teams (PATH & DAIDS).
- FHI M&E indicators for dissemination were incorporated into INFO's "Guide to Monitoring and Evaluating Information Products and Services," which will be used widely by CAs.
- The development / implementation of a communications plan for the Ghana Savvy study resulted in a positive response by the community, activists and news media and avoided potential controversy.
- Sixty-nine percent of the 1,452,422 visits to FHI's Web site were to RH materials, 40% of which were from outside the US.
- PAHO's 2005 Spanish translation of FHI's field guide on qualitative research has made modern research methodologies available to hundreds of SRH researchers in Latin America.
- Media contacts to FHI nearly quadrupled, and an estimated 100 million people were exposed to media coverage that mentioned FHI's research and programs in some capacity. Findings from FHI's Cochrane Review on oral contraceptives and weight gain were reported in major print (reaching over 15 million) and broadcast media (additional millions) in the US, Europe and Latin America. Promoted media coverage of FHI's NEJM commentary about condoms and HPV, successfully reaching over 49 million people (print media sources with a total circulation of over 15 million, and listservs/Web sites reached almost 35 million additional readers). Was also picked up by 43 broadcast media sources, including CNN and CBS News.
- FHI's checklists were described in detail in a Global Health Technical Brief, "Five Simple Ways to Improve Oral Contraceptive Provision and Use," published by INFO in April, 2006.
- FHI's pregnancy, COC, DMPA, and IUD checklists were the basis of a Global Health Technical Brief, "Checklists Reduce Medical Barriers to Contraceptive Use" published by INFO in April, 2006.
- FHI, INFO and others drafted the "Contraceptive Effectiveness Chart" for the Global Family Planning Handbook (in press). INFO project is translating into Spanish, French, and Portuguese.
- FHI's IUD Checklist was printed in Population Reports, Vol. 33(2), February 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: Implementing Best Practices Consortium (FCO 113116)

Technical Monitor: AJaggi
Collaborating Agency(s): US Agency for International Development; World Health Organization (WHO); Population Council; EngenderHealth

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify how FHI's institutional goals can dovetail with those of the IBP.
2) To incorporate partnerships with the IBP into existing workplans and strategies.
3) To increase utilization of the IBP's Electronic Communication System (ECS) among FHI staff and in-country partners.

Note: This subproject was modified from the 2005-06 workplan due to a reduction in funding levels. The above ATI objectives were contained in the Approval to Implement letter and was submitted on December 30 2005.

Description: FHI is a founding member of the Implementing Best Practices (IBP) Initiative, which was established in 1999 by the World Health Organization's Reproductive Health and Research Unit (WHO/RHR). A formal consortium, which is now comprised of over 20 partner agencies, including the USAID, was established in 2001. The primary goal of the IBP is to improve access to and quality of reproductive healthcare through a systematic approach focused on developing and supporting strategies that introduce, adapt, and apply evidence-based practices in reproductive health. Initiatives such as the IBP have the potential to improve reproductive health outcomes by expanding the quality and reach of reproductive health services worldwide.
Under this subproject, FHI will contribute staff time and resources to sustain active membership in the Consortium and to support activities in the IBP program of work. The subproject will primarily contribute to fulfillment of FHI's mandate to ensure that relevant research findings are broadly disseminated and utilized.
By nature, participation in the IBP Consortium will involve coordination and collaboration with other member agencies, including USAID, WHO/RHR, and several CA's and international partners.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI transferred chairmanship to IntraHealth (September 2005).
- The IBP intern compiled IBP's standard operating procedures and created an IBP orientation binder for the new chair and steering committee (completed October 2005).
- FHI organized an IBP panel at APHA (December 2005). The panel was titled "Implementing Best Practices Initiative: A Global Collaboration." Presentations included the following: overview of the Implementing Best Practices (IBP) Initiative: A global collaboration by Margaret Usher-Patel; SPARHCS Framework: Developing a strategic commitment for ensuring commodity security by Lisa Hare, Chris Wright, and Wendy Abramson; Performance Improvement: A tool for action planning to implement best practices by Pape Gaye and Lauren Crigler; Use of a virtual collaboration system to support sharing effective practices in reproductive health by William Finger, and Margaret D'Adamo; and Introducing a Best Practice: Evidence-Based Provision of the Standard Days Method by Victoria H. Jennings, Bulbul Sood, and Caroline Blair.
- FHI organized a Steering Committee meeting and a Coordinating Committee meeting during APHA. Proceedings are available from the trip reports of J Smith and B Finger.
- FHI developed a proposal on behalf of IBP to conduct an Experts Panel on research utilization for consideration of GLP funding ($120,000). However, the proposal was not funded for FY 06-07.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 10, 2006.
- Anuj Jaggi was assigned as the Technical Monitor for the subproject (May 2006).
- FHI participated in the Steering Committee meeting & Organizing Committee meeting; both were held at the Global Health Council, and Dr. Smith attended.

- Staff extended the subproject end date to June 2007 and submitted a request for an additional $25,000 for FY 06-07.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 20,000	**Projected End Date:**	Jun 2007

Worldwide: CRTU Network of Champions (FCO 113113)

Technical Monitor: EMcGinn

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): 1) To implement and evaluate a network approach to enhance RtoP. 2) To support "change agents'" efforts to introduce or facilitate evidence-based change at the programmatic or policy level in-country. 3) To increase partnerships in the field, primarily through memorandums of understanding (MOU) with the champions' home agencies. 4) To improve local input into FHI's research agenda, strengthening the important link between practice and research.

Note: Objectives were updated 7/06 in an effort to make them more specific to the proposed activities and projected outcomes of the project.

Description: The process of research utilization aims to bridge the gap between research and practice by ensuring that policy-makers, health practitioners, or other decision-makers are able to access, understand, and implement recommendations stemming from new research findings in a timely and efficient manner. Applying the principles of Everett Rogers' Diffusion of Innovations Theory, research utilization literature asserts that access to, understanding, translation, and uptake of research findings can be facilitated by influential local opinion leaders who assume the role of advocates or "change agents." In line with the change agent model, the proposed subproject will build on lessons learned from FHI's experience with the innovative pilot Network of Champions subproject implemented under the CTR agreement (FCO 3305).

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Activities, Accomplishments, Problems through December 31, 2005

- The evaluation of the FY 04-05 Network of Champions subproject was completed with recommendations on what aspects of the effort should continue or be altered.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 10, 2006.
- Initiation of this new subproject was delayed pending result of the FY 04-05 evaluation and a clearer definition of the focus country program.
- Internal consensus was reached on how to revise the subproject.
- A strategic plan was developed for the Network of Champions and the thematic focus of FP and HIV was decided.
- The following target countries were chosen for the subproject: Tanzania, Zambia, Uganda and Nigeria.

Findings and Outcomes:

- Some key recommendations from the Network of Champions subproject under the CTR were as follows:
- Integrate the subproject within existing networks and professional associations such as, linking the Champion with the National Reproductive Health Task Force within the Ministry of Health.
- Establish formal collaboration, perhaps in the form of a MOU, with each Champion's affiliated institution. This will both serve to encourage interest and support for the Champion's activities, and will also provide an ideal opportunity to establish an important relationship with key in-country partners. Rather than relying on one individual to effect change, the initiative will be backed by the momentum of an entire institution.
- Where possible, manage 'Champions' from the field office.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 255,000	**Projected End Date:**	Jun 2007

Worldwide: Research to Practice Leadership (FCO 113114)

Technical Monitor: EMcGinn
Collaborating Agency(s): CONRAD; Management Sciences for Health (MSH); World Health Organization (WHO); Population Council; PATH; EngenderHealth; Save the Children

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): 1) To provide internal technical assistance & strengthen capacity building for research utilization (RU); 2) to identify RtoP priority topics and strategies; and 3) to develop, maintain and implement memorandums of understanding (MoU) with key partners.

Description: Public health research is not an end in itself; rather, it is intended to improve service delivery, policies, and practices. Yet, the gap between existing evidence and clinical and programmatic practice is substantial, with policy and practice changes often lagging well behind the evidence, despite substantial investments in research.
Under the CTR, FHI undertook the Research to Practice Initiative (RtoP), FCO 3003, as a concerted effort to reduce this gap by establishing more effective links between researchers and service delivery organizations to both promote new and under-used research findings, and identify research questions that would address current issues in service delivery.
Under the CRTU Project, this RtoP Leadership subproject will support the strengthening of capacity to promote research utilization and serve as the principal vehicle for developing, maintaining and implementing a network of Global MOU partnerships. MoU partnerships will help inform FHI's research priority-setting process to ensure that future research addresses current service delivery needs. In addition, strong partnerships will facilitate adoption of research findings and thereby enhance impact on policies and programs.

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Activities, Accomplishments, Problems through December 31, 2005

- RtoP attended the Repositioning FP meeting on November 10, 2005 and reported back on opportunities to collaborate with the task force.
- A mechanism for implementing MoUs with partners was initiated, including hosting an internal meeting to orient relationship managers and follow-up orientation meetings with each CRTU division.
- Meetings were held with ADRA, Save the Children, and MSH to discuss joint development of work plans.
- An FHI display board was created to document partnership activities.
- Two new staff members were hired (August and December 2005) to replace two staff members who departed (July and October 2005).
- Eleven subprojects were initiated (whole or in part) by RtoP during RY 05-06 of the CRTU.
- Two subprojects for RY 06-07 were developed for FHI's priority setting process, and technical assistance was offered to FHI staff seeking RU input into their concept proposals.
- McGinn responded to requests for technical presentations on LAPMs for Operations Research Corporation (ORC) Macro and UNC's MCH MPH Program (November 2005).
- RtoP staff participated in the development of CRTU RU indicators and an RU database.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 12, 2006.
- RtoP staff held a retreat in January 2006 to focus on vision/mandate/team-building.
- Relationship Mgrs were established to oversee each MoU partner, and systems were established, including an MoU matrix, and an RU indicators report.
- In April 2006, electronic versions of the checklists were posted in 12 RH/FP listservs/online databases/newsletters, e-mailed to 4,439 persons present in the Online Rolodex, and 5 external non-FHI Web sites linked to the FHI Web site for this checklist (FCOs 113112 / 113107).
- In June 2006, a new version of the COC Checklist was developed and made available in four languages: English, Spanish, French, and Kiswahili. This subproject also supported the cost of translating the DMPA checklist into French, Spanish, and Kiswahili (FCOs 113112 / 113107).
- As of June 2006, a total of 10,500 laminated COC checklists were printed in English, Spanish, and French (co-funded by FCO 113118). Of these, 25% have been distributed in response to requests from Madagascar, South Africa, Dominican Republic, Tanzania, and Romania.
- The COC checklist has been endorsed and co-branded by the MOH in Uganda. In-country dissemination plans for Kenya and Uganda to reach district level health providers, managers, and trainers have been developed (FCOs 113112 and 113107).
- The checklist was featured at the FP Program Design, Monitoring and Evaluation (PDME) Workshop in Dar, Tanzania (Feb 2006) and at the Global Health Conference (May 2006).
- A small effort to move FHI's checklists into practice was initiated in the DR as a result of FHI TA on a local workshop. This FCO supported the set-up and initiation of a plan to document the distribution of checklists being used by a local non-profit organization, CONAPOFA, to help train FP providers. An M&E plan was developed and a consultant hired to implement the work.
- Staff collaborated with JPHIEGO to organize a CBD of DMPA briefing for about 20 people.

Findings and Outcomes:

- The COC checklist has been endorsed and co-branded by the MOH in Uganda.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 1,250,000	**Projected End Date:**	Apr 2010

Worldwide: USAID Best Practices Package: Development and M & E (FCO 113115/123101)

Technical Monitor: EMcGinn
Collaborating Agency(s): Population Council; EngenderHealth
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop strategies and tools to enhance timely and convenient delivery of contraceptive methods; 2) to change policies and guidelines to reflect new research findings; 3) to facilitate increased acceptance, support for, and uptake of contraceptive methods; 4) to facilitate USAID HPN officers oversight of the design and evaluation of country-level family planning programs; 5) to identify and market in collaboration with USAID, an improved coordination among cooperating agencies (CAs) to promote a basic package of best practices for FP/RH programs; and 6) to facilitate increased funding for and implementation of RH best practices (BPP) at the country level.

Description: Reproductive health research over the past decade has yielded a number of practices, which, if widely incorporated into practice, have the potential to greatly improve the reproductive health and family planning options of individuals worldwide. Practices such as advance provision and Quick Start of oral contraceptives (OCs), for example, can help reduce the medical barriers new clients may face when seeking to begin OC use. Similarly, specially designed screening tools such as the "Pregnancy Checklist" can expand access to high quality family planning services by strengthening the capacity of community-based workers.

Although such practices have been acknowledged as applicable to many family planning and reproductive health programs, most have not been widely implemented. There is a significant need among FP/RH programs to identify locally-relevant practices which can strengthen both quality and accessibility of services.

FHI proposes to participate in a collaborative effort to develop and field test a package approach to promoting RH best practices. This process will be carried out in collaboration with USAID Missions, the Office of Population and Reproductive Health, and other key partners such as EngenderHealth, the Population Council, and The Adventist Relief Agency.

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Activities, Accomplishments, Problems through December 31, 2005

- A "USAID Best Practices Package" concept proposal was developed.
- The Madagascar Mission signaled interest and a team comprised of USAID, FHI, and ADRA conducted an assessment (March-April 2006).
- An assessment report and recommendations were submitted, and Madagascar has chosen five practices for implementation during the 2006-2007 fiscal year: Systematic screening, CBD of DMPA, and implementation of FHI's four provider checklists (COC, DMPA, IUD, Pregnancy).

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Madagascar was identified as a country interested in piloting the BPP, and a team comprised of USAID, FHI, and ADRA conducted an assessment and met with stakeholders (March/April 2006).
- As a result of these activities, FHI is working to designate Madagascar as a Focus Country, and implementation of the BPP will be led by FCP staff.

Funding Source(s):	USAID - US Agency for International Development/CSL-Core; USAID - US Agency for International Development/Core		**FCO Approved:**	**113115** Sep 2005 **123101** Feb 2006
Total Approved Budget:	**113115**	$ 150,000	**Projected End Date:**	Jun 2007
	123101	In Approval		

Kenya: Evaluation of What's New & Cool for Youth Booklet (FCO 143101)

Technical Monitor: EMartin
Collaborating Agency(s): National Coordinating Agency for Population and Development (NCAPD)

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To inform the National Coordinating Agency for Population Development (NCAPD) on how to maximize exposure to the "What's New and Cool for Youth" booklet among Kenyan youth, thereby equipping them with knowledge, skills and attitudes to make informed decisions about their reproductive health needs and rights. More specifically, this proposed subproject aims to:
1) Create consensus among key stakeholders (including NCAPD and the Kenya Institute of Education) on the best strategy to reach in- and out-of-school youth with the booklet;
2) pilot-test the distribution and utilization of the booklet and related orientation tools;
3) assess whether the booklet can help improve awareness of RH issues among youth; and

4) identify lessons learned that may inform NCAPD's efforts to scale up the booklet distribution to other districts in Kenya.

Description: To address the need to provide Kenyan youth with adequate reproductive health and HIV/AIDS information, the National Coordinating Agency for Population and Development (NCAPD), with technical assistance from Family Health International (FHI) and financial support from USAID/Kenya has produced a booklet entitled "What's New and Cool for Youth." The booklet aims to reach both in- and out-of-school youth aged 10-24 years with information on various issues such as the relationship between population and development, rights and responsibilities, family planning, HIV/AIDS, and setting short- and long-term goals for various aspects of life including schooling, friendships, and other personal interests. The booklet was launched in August 2005 and plans are underway to distribute it nationwide. Building on the activities and accomplishments achieved under FCO 3446, this subproject will continue FHI's collaboration with NCAPD to inform NCAPD's scale up of booklet distribution to in- and out-of-school youth in Kenya.

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Activities, Accomplishments, Problems through December 31, 2005

- Under FCO 3446, 5,000 copies of the booklet entitled "What's New and Cool for Youth" and 10,000 copies of a summary brochure were produced. The booklet was successfully launched in August 2005 with over 100 stakeholders, including the Ministry of Health, Ministry of Education, African Youth Parliament, Kenya Scouts Association, Kenya Girl Guides Association, Marie Stopes/Kenya, and the Policy Project.
- FCO 3446 was closed on August 31, 2005.
- The follow-on evaluation component to be conducted under FCO 143101 was approved under the CRTU Year 1 work plan.
- A draft protocol was developed to pilot test the distribution and utilization of the booklet and to gather information about the effectiveness of the booklet in improving awareness of reproductive health issues among in-school youth.
- Field support funds were received, and an Approval to Implement (ATI) letter was submitted in December 2005.
- A consultant was identified to translate the booklet into Kiswahili. Also, a local consultant was identified to work on development of orientation tools designed to be used by teachers, staff of youth-serving organizations and parents to support utilization of the booklet.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In collaboration with NCAPD, FHI supported one regional dissemination meeting in Nyanza province in February 2006.
- The draft protocol was reviewed by the project team as well as FHI staff including the Kenya Project Director. Feedback was incorporated and the protocol finalized in April 2006.
- The baseline survey was drafted. It was reviewed internally by FHI project team members, including representatives from both HSR and BIOS, and externally by NCAPD. Feedback was incorporated and the baseline data collection form finalized.
- The protocol was submitted to PHSC, and ethical approval was received through expedited review in May 2006.
- In June 2006, the protocol was submitted for local ethical review to the National Council for Science and Technology in June 2006.
- Approval was obtained from the Ministry of Education to conduct evaluation in schools within two districts of Nyanza Province, Siaya and Rachuonyo.
- Comments and feedback on the booklet were obtained from the Kenya Institute of Education Review Committee.
- An initial draft of the facilitators' guide was prepared for teachers and staff of youth-serving organizations to support utilization of the "What's New and Cool for Youth" booklet. The guide includes supplemental information on topics presented in the booklet as well as exercises

and activities for the facilitator to complete with youth in order to strengthen, improve and increase their understanding of RH issues and information covered in the booklet.
- A draft translation of the booklet text in Kiswahili was completed by the consultant and reviewed by FHI/Nairobi staff.
- Due to continued delay in the publication of the study results on hormonal contraception and HIV acquisition, the Project Director initiated discussions with USAID/Kenya to reprogram field support funds no longer needed for activities under FCO 143103 to support ongoing activities under this subproject.

Funding Source(s):	USAID - US Agency for International Development/Field Support	**FCO Approved:**	Dec 2005
Total Approved Budget:	$ 170,000	**Projected End Date:**	Apr 2010

Nigeria: Evidence-based Child Spacing Intervention Development for Northern Nigeria (FCO 143104)

Technical Monitor: WCastro

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To conduct an assessment to understand: (a) the barriers to the uptake of FP methods in northern Nigeria; and (b) best practices in promoting family planning in this region, and similar areas (e.g. Sahel countries); and 2) to design and test a promising intervention to improve family planning uptake in this region working with the assessment conclusions.

Description: This subproject will serve to identify and implement a promising family planning/child spacing intervention in northern Nigeria, a region with low modern contraceptive use and poor reproductive health indicators. Information generated from this effort will add to the knowledge base about how to increase demand for and utilization of family planning services and will directly inform the development of targeted programs to reposition FP in northern Nigeria.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The FCO for this subproject was opened on April 10, 2006.
- FHI drafted a scope of work to hire a consultant to conduct a desk review of currently available information on what is known about barriers and best practices in promoting family planning in this region and similar areas (e.g. Sahel countries and other Muslim areas). A potential consultant was identified in Nigeria.

Funding Source(s):	USAID - US Agency for International Development/Field Support	**FCO Approved:**	Apr 2006
Total Approved Budget:	$ 250,418	**Projected End Date:**	Oct 2007

Kenya: Building Strategic Information Capacity within NASCOP (FCO 153102)

Technical Monitor: MKuyoh
Collaborating Agency(s): Kenyatta Univ. School of HS; National AIDS/STI Control Programme (NASCOP)

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To strengthen national systems for strategic information and operations research in order to improve reproductive health (including HIV/AIDS) programming, implementation, monitoring, and evaluation. FHI will work with Kenyatta University's School of Health Sciences and the National AIDS and STI Control Programme (NASCOP) to: 1) train four students (3 Master's and 1 PhD) in strategic information collation, analysis and interpretation; and 2) identify key RH/HIV program areas with gaps in strategic information and address these through the students' thesis reports.

Description: One key component of Kenya's annual PEPFAR Country Operational Plan (COP) is continued support for national surveillance and monitoring systems in order to document outcomes and evaluate the impact of PEPFAR-supported and national HIV/AIDS program activities. This subproject will build capacity in the areas of research design, monitoring and evaluation, and using data for decision-making at NASCOP and other institutions active in reproductive health and HIV/AIDS programming in Kenya. With technical support from FHI/IFH, the Division of Reproductive Health (DRH), NASCOP and Kenyatta University are undertaking four targeted evaluations designed to address key reproductive health and PEPFAR goals in Kenya. The topics for these evaluations were identified jointly by FHI, Kenyatta University, NASCOP, DRH, the USAID strategic information team in Kenya, and local PEPFAR program managers. In order to implement these evaluations, the Technical Monitor will mentor four graduate students at Kenyatta University whose theses research will contribute to the evaluation activities. The technical support and assistance provided by FHI will respond not only to the needs of the selected students, but also NASCOP's monitoring and evaluation unit, and the Mission's strategic information priorities.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on February 2, 2006.
- The technical monitor, PNgom supported the four graduate students in conceptualization and development of their proposals.

- The graduate students submitted their proposals to the local IRB at the Ministry of Sciences and Technology (MOEST) for clearance to conduct the studies.
- A one-week research/monitoring and evaluation workshop was conducted for the four graduate students by Kenyatta University in March 2006 with technical support from FHI/Nairobi.
- Secondary data collection was undertaken by the four graduate students.
- The technical monitor supported the 4 students as they finalized their proposals.
- All four students initiated primary data collection to fill in gaps in information obtained from the secondary data by June 2006.

Funding Source(s):	USAID - US Agency for International Development/PEPFAR	**FCO Approved:**	Aug 2005
Total Approved Budget:	$ 137,000	**Projected End Date:**	Sep 2006

Worldwide: Research Ethics Training Curriculum for Community Representatives (RETC-CR) (FCO 172000 and previously 1398/1600/1601/2710)

Technical Monitor: DBorasky
Collaborating Agency(s): Mellon Foundation; NIH
Status: Ongoing
Group: OIRE

Objective(s): To provide basic education to community representatives on the essential ethical questions that must be considered when research is being planned and conducted. The Research Ethics Training Curriculum for Community Representatives (RETC-CR) will empower community representatives to have meaningful participation in the research process.

Description: Increasing recognition and importance is being given to the participation of community representatives in the entire research process. This participation may be obtained by identifying specific community representatives or by the establishment of Community Advisory Boards (CABs). Community involvement optimizes the protection of research participants, enhances investigator's perception of the research goals, improves the way research is designed, and ensures that research is responsive to community needs and expectations. In the initial planning of this project, we were unable to find a similar educational tool. The new curriculum is based on FHI's experience in developing our previous Research Ethics Training Curriculum, which was designed for research staff. The curriculum has 4 main components: Content, Case Studies, Evaluation and References. The content section covers the material to be learned. It is composed of images and a narrative text. The case studies include actual research studies conducted by FHI. The evaluation section provides an evaluation form of the curriculum, and the reference section includes selected reading materials in the research ethics field.
This curriculum has become a standard training tool for many national and international organizations. The RETC-CR development is the responsibility of FHI's Office of International Research Ethics, with the participation of Field, Information and Training Services, HIV Prevention Trials Network and the Behavioral and Social Sciences Research Group. The RETC-CR is designed to be used either as an interactive self-study program or a participatory group training experience. Completing the curriculum takes approximately 11 hours. It is anticipated that in settings where participants might have limited formal education, a group training conducted by a trained facilitator may be the best approach.

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Activities, Accomplishments, Problems through December 31, 2005

- In February 2004, the first draft was reviewed in-house by FHI staff with experience in research ethics and community participation.
- In March-April 2004, the second draft was reviewed by 13 international experts in the field, including experts from the anticipated sites of the future field tests.
- In May-June 2004, the third draft was field-tested in actual workshops organized for community representatives in Brazil, India, Malawi, USA, Zimbabwe and Zambia. A structured field test protocol was developed for this purpose.
- In October 2004, the final version of the English curriculum was completed and a total of 2,000 CD-ROMs and 2,000 brochures were printed.
- The Spanish and French translations of the curriculum were completed in December 2004.
- The English RETC-CR was showcased at the 2005 HPTN Annual meeting held February 14-18, 2005 in Washington, D.C.
- Copies of the curriculum have been distributed to the entire membership of the Forum for Ethical Review Committees in Asia and Western Pacific Region (FERCAP), The Latin American Forum of Ethics Committees for Health Research (FLACEIS) and The Pan-African Bioethics Initiative (PABIN). In addition, the curriculum has been distributed to selected individuals of major organizations including NIH Institutes, the Office for Human Research Protections (OHRP) and The World Health Organization (WHO).
- FHI staff from the IT department completed the development of the CD-ROM and Web versions of the English, French and Spanish curricula.
- The RETC-CR Instructor's Guide for Training-of-Trainers was completed in October 2005. This guide is similar to the guide produced for our Research Ethics Training Curriculum, and will enhance the impact of the RETC-CR by enabling trainees to train other community representatives.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI staff from the IT department started working towards the development of the four-language CD-ROM as well as the Web version of the Portuguese curriculum.

Findings and Outcomes:

- In March 2005, the RETC-CR received the 2004-2005 Distinguished Award of the Society for Technical Communication (STC), which is the highest award of this society. It also received the Merit Award at the STC International competition.
- In December 2005, the RETC-CR received the Best Practice Award for Excellence in Human Research Protection from the Health Improvement Institute. This annual award is given for demonstrated excellence in protecting and promoting the well-being of people who participate in research.

Funding Source(s):		Mellon Foundation; USAID - US Agency for International Development/OYB	**FCO Approved:**	**1600**	Apr 1999
				1398	Mar 2002
				1601	Feb 2002
				2710	Jul 2004
				172000	Sep 2005
Total Approved Budget:	**1600**	N/A	**Projected End Date:**		Dec 2006
	1398	N/A			
	1601	$ 7,514			
	2710	$ 50,000			
	72000	$ 100,000			
		$ 157,514			

Worldwide: BASS Technical Leadership (FCO 116103)

Technical Monitor: CGeary

Status: Ongoing
Group: BASS

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide staff time for completing papers begun under the CTR Program, developing concept proposals for workplans, working on research synthesis, and external consultations.

Description: This subproject has been created to facilitate completion of papers begun under the CTR as well as to finance the development of new research concepts.

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Activities, Accomplishments, Problems through December 31, 2005

- Amy Corneli developed a concept proposal with Greg Guest and Markus Steiner; "Improving Self-report Measures using Biomarkers and In-depth interviews".
- The final report, “Consistent Condom Use among Ugandan Couples in Primary Relationships,” was prepared by five co-authors and is under final review. It will be disseminated to those involved in the research and will be the reference document for presentations and papers to be submitted for publication. Those papers are: (1) Breaking the Ice: Introducing Condoms into Stable Relationships in Uganda; and (2) Learning to Accept the Condom.
- Tolley participated as a behavioral expert in a Clinical Trials Working Group meeting held in London, England on October 10-11, 2005. The objective of the working group meeting was to draft a microbicide development strategy which was presented to funders in Seattle, WA in November 2006.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Two papers were submitted for publication and presentations made at FHI and at least one professional meeting (PAA) in late March 2006.
- Kate MacQueen completed paperwriting on "Adolescents and HIV clinical trials: ethics, culture, and context."
- Work was initiated to develop research on pregnancy in microbicide trials.
- A review paper on Vasectomy Acceptability was begun.
- Work was also done on a paper on recruitment of microbicide trial participants.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Sep 2006

Worldwide: BIOS Technical Leadership (FCO 119100)

Technical Monitor: DTaylor

Status: Ongoing
Group: BIOS

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop biostatistical research subprojects to be funded under the CRTU; and 2) to prepare papers that report on findings of BIOS research funded under the CRTU.

Description: This subproject funds the time that various members of BIOS spend in preparing concept papers in these areas. Once approval has been received to proceed with a concept paper, an FCO will be assigned. The subproject also funds the preparation of papers for which the research was funded under the CTR.

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Activities, Accomplishments, Problems through December 31, 2005

- During the period of July 1, 2005 through December 31, 2005, Biostatistics staff contributed to the development of concept proposals for projects under review for inclusion in the 2006-07 workplan. Biostatistics staff provided preliminary design consultation and sample size calculations.
- Work continued on a statistical research subproject (initiated under FCO 9102 in the prior cooperative agreement) designed to better understand the impact of nonrandom censoring in contraceptive effectiveness trials and to develop analytical approaches that would reduce bias caused by informative censoring. This subproject evaluates the use competing risk and joint modeling survival methods for barrier contraceptive trials with high discontinuation rates.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Biostatistical consultation for new concept proposal development continued.

- A paper on the use of breakage/slippage as surrogate endpoints for condom effectiveness (begun during the prior cooperative agreement) was completed in October 2005.
- A paper reporting the findings and recommendations of statistical research on the use competing risk and joint modeling survival methods for barrier contraceptive trials with high discontinuation rates was submitted to Journal of Biopharmaceutical Statistics in January 2006.
- Available datasets were used to assess the relationship between time-varying self-reported risk factors (e.g., condom use, coital frequency) and risk of clinical outcomes such as unexpected pregnancy to help determine the utility of various self-reported variables.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: CRD Technical Leadership (FCO 112120)

Technical Monitor: LDorflinger

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To develop clinical research subprojects to be funded under the CRTU; 2) to support time of key staff to provide technical leadership to partners and organizations, including participation in relevant meetings; and 3) to prepare papers that report on additional findings of clinical research activities funded under the CTR.

Description: This subproject funds the time that various members of CRD spend in developing ideas and preparing concept papers in strategic areas of the CRTU, including collaborations with HSR, BASS, FITS and BIOS staff. Once approval has been received to proceed with a concept, an FCO will be assigned for further work. The subproject also funds the contribution of CRD staff to interagency committees and other decision making groups involved in the development and evaluation of contraceptive products and services of interest to USAID. Finally, a number of key research activities were completed under the CTR for which additional analyses, papers and Research to Practice documents were anticipated but not completed because of time; these will be funded under this FCO.

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Activities, Accomplishments, Problems through December 31, 2005

- Staff worked on developing the description of a vasectomy devise that might be patentable. A disclosure document was submitted to the US Patent Office on September 25, 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI staff:
- Completed a chapter on the contraceptive patch and ring for contraceptive technology which was finalized in March 2006.
- Began drafting a manuscript for the Quick start study.
- Participated in meetings to discuss contraceptive discontinuation with FITS.
- Participated in meetings with FITS/WHO IBP to discuss opportunities for collaboration.
- Reviewed and revised several research-related SOPs and P&Ps from January-June 2006.
- Reviewed several manuscripts for journals from January-June 2006 and the following titled "Magnesium-Sulfate Tocolysis: Time to Quit" was accepted for publication by Obstetrics and Gynecology.
- Wrote and had published in the New England Journal of Medicine 2006;354:2642-43 a paper titled: "Condoms and HPV: Science, public health and the common ground"
- Wrote and submitted a paper titled "Pain from IUD insertion: trial of prophylactic ibuprofen" during the period February-June 2006.
- Submitted abstracts were accepted for oral presentation at the ARPH and FIGO 2006 in March and June 2006.
- Staff also:
- Made preparations during the period April-June 2006 as a speaker for the 5th International Symposium on IUDs.
- Wrote a manuscript titled "Pregnancy among sex workers participating in a condom intervention trial highlights the need for dual protection". It derives from the Madagascar trial of male and female condom promotion.
- Drafted a manuscript summarizing the results of the final report produced for USAID "Identifying Appropriate Candidates for IUD Insertion in Moderate to High STI Setting: The IUD Algorithm Project (March 2003). The manuscript was circulated to authors in June 2006.
- Drafted a manuscript titled: "Is it safe to reuse female condoms? A Randomized Controlled Trial".
- Made communications with the International Journal of STD and AIDs regarding the publication of an article on FC Reuse.
- Continued making progress on finalizing a vasectomy manuscript that is nearly ready for submission to a journal.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 213,047	**Projected End Date:**	Aug 2006

Worldwide: HSR Technical Leadership (FCO 114106)

Technical Monitor: BJanowitz

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To develop health services research subprojects to be funded under the CRTU.

Description: FHI strategies under the new CRTU emphasize increasing the acceptance and continued use of existing methods of contraception and of integrating FP into HIV services. HSR's research aims to find ways of increasing access, quality and efficiency of service provision to accomplish these goals. As a result, our research should lead to greater acceptance and higher continuation rates of methods and thus to important public health outcomes.
This subproject funds the time that various members of HSR spend in preparing concept papers in these areas. Once approval has been received to proceed with a concept paper, an FCO will be assigned. This FCO also funds the writing of papers from studies conducted under the CTR and CRTU, and the dissemination of results.

2005—06 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2005

- Concept proposals for new CRTU subprojects were developed.
- Heidi Reynolds attended the APHA conference and presented "Integrating family planning services into voluntary counseling and testing for HIV in Kenya: Results of operations research" in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Concept proposals for new CRTU subprojects were developed.
- Chin-Quee DS, Cuthbertson C, Janowitz B. "Over-the-counter pill provision: Evidence from Jamaica" was published in Studies in Family Planning, June 2006. [Pub#2006-38]
- Reynolds HW, Janowitz B, Homan R, Johnson L. "The value of contraception to prevent perinatal HIV transmission" was published in Sexually Transmitted Diseases, June 2006. [Pub#2006-32]
- Chin-Quee DS, Wong, E, Cuthbertson, C. "Evaluating Information on Oral Contraceptive Use: A Randomized Controlled Trial to Assess Missed Pill Instructions" is in press at Human Reproduction. [Pub#2004-027]
- Thomsen S, Ombidi W, Toroitich-Ruto C, FHI Analysis Team, Homan R, Luchters S. "A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa" was submitted, received reviews, and re-submitted to STI journal. The manuscript was accepted for publication. [Pub#2005-055]
- Wesson submitted "Provider views on the acceptability of an IUD checklist screening tool" to Contraception.
- Hatzell T, Feldblum P, Van Damme K, Rasamindrakotroka A, Nasution M, Wong E, Ralimamonjy L, Raharimalala L. "Temporal Trends in STI Prevalence and Condom Use Following Introduction of the Female Condom to Madagascar Sex Workers" was submitted to

Lancet, and revised for AIDS. The paper was revised and is currently under review with STI. [Pub#2005-022]

- Hatzell served as co-author on "Increased risk of chlamydial and gonococcal infection in adolescent sex workers" in collaboration with UNC. Preliminary acceptance by STD is pending revisions.
- Hatzell advanced preparation of manuscripts based on the Madagascar female condom trial. Hatzell completed the final report, Testing the Integration of Dual Protection Counseling into Family Planning Clinics in Ethiopia, and Characteristics of High-Performing PMTCT Services in South Africa.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	N/A	**Projected End Date:**	Apr 2010

USA: Development of Guidelines for Contraceptive Users (FCO 112110/172003 and previously 2706)

Technical Monitor: KNanda
Collaborating Agency(s): World Health Organization (WHO); National Institutes of Health (NIH); Centers for Disease Control and Prevention (CDC)

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To develop and implement a system to ensure that the "Medical Eligibility Criteria" and the "Selected Practice Recommendations" remain current and based on the best available science. The system provides for ongoing monitoring and critical appraisal of available evidence and assures that this information is available for updating guidance.

Description: The World Health Organization (WHO) provides evidence-based family planning guidance for use worldwide. WHO currently has two such guidelines, Medical Eligibility Criteria (MEC) for Contraceptive Use and Selected Practice Recommendations (SPR) for Contraceptive Use, which are widely used globally and often incorporated into national family planning standards and guidelines. These documents are the first evidence-based, global consensus guidelines that address 'who' can safely and effectively use contraceptive methods (the "Medical Eligibility Criteria") and 'how' to safely and effectively use contraceptive methods (the "Selected Practice Recommendations"). A third guideline, the Handbook for Providers, is currently in development.
To ensure that these guidelines remain up-to-date, WHO, in collaboration with CDC and the INFO Project at JHU, developed the Continuous Identification of Research Evidence (CIRE) system to identify, synthesize, and evaluate new scientific evidence as it becomes available. The second component of the system, conducted by CDC and WHO, and assisted by FHI, consists of:
1) determining which new research reports are relevant;
2) critically appraising new, relevant reports;

3) preparing or updating systematic reviews;
4) obtaining peer review of systematic reviews and revising as appropriate; and
5) providing final systematic reviews to WHO Secretariat.
FHI staff are also involved in several chapters of the Handbook for Providers, serve as peer-reviewers on an ongoing basis for reviews generated from the CIRE system, and provide technical leadership by participating in WHO Expert Working Group meetings and other assistance to WHO secretariat as needed. This leadership role also involves identifying research gaps identified by the systematic reviews and Expert meetings, and working with WHO to fill these research needs.

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Activities, Accomplishments, Problems through December 31, 2005

- USAID approved this subproject in August 2003.
- The initial activity of the system, conducted by JHU/CCP, began. It consisted of an ongoing, comprehensive bibliographic search.
- CDC, assisted by FHI, conducted the following activities: 1) determined which new pieces of evidence were relevant; 2) critically appraised new evidence; 3) sent critical appraisals for peer review and, subsequently, created final appraisals; and 4) conducted systematic reviews.
- WHO held the third Expert Working Group for the "Medical Eligibility Criteria for Contraceptive Use" in fall 2003.
- The Medical Eligibility Criteria Guidelines were revised and are available on the WHO Website.
- For the April 2004 WHO Meeting of the Expert Group for the "Selected Practice Recommendations for Contraceptive Use", CDC and FHI updated prior systematic reviews and conducted new systematic reviews.
- WHO held the second Expert Working Group Meeting for the Selected Practice Recommendations in April 2004.
- The Selected Practice Recommendations were revised based on data presented at the meeting. They were posted on the WHO Website in 2005.
- Selected systematic reviews, including a review of progestin-only contraception and age, were updated with recent data.
- The review of progestin-only contraception and age (including new data on effects on bone density) was sent to the Guidelines Steering Group.
- WHO convened a consultation in Geneva, on June 20-21 2005, to assess current evidence on the relationship between the use of steroid hormonal contraceptives and bone health.
- USAID FCO 2706 was closed in September 2005. Activities are continuing under the CRTU (FCO 112110).
- A conference call of WHO-CDC staff was held on November 1, 2005 to discuss CIRE activities since June 2005, to review systematic reviews completed since the last quarterly call in February 2005, and to consider submitting systematic reviews to the Reproductive Health Library at WHO to enable a wider dissemination of systematic reviews to professionals in developing countries.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The following reviews were updated:
- SPR14: Can a woman receive an advance supply of emergency contraceptive pills (ECPs)?
- SPR 13: How can a woman take emergency contraceptive pills (ECPs)?
- SPR 23: What can be done if a woman experiences menstrual abnormalities when using implants?
- LNG-IUD and Endometriosis
- LNG-IUD and Menorrhagia
- COCs and Immobilization
- Hormonal contraception and anticonvulsants

- SPR 18: What can a woman do if she misses progestogen-only pills (POPs)?
- Ten systematic reviews from evidence identified through CIRE that was presented at the 2003 MEC meeting and the 2004 SPR meeting were published in the February 2006 issue of Contraception.
- Two systematic reviews presented during a technical consultation on hormonal contraception and bone health were published in the May 2006 issue of Contraception.
- FHI updated the MEC chart to include sickle cell anemia as a condition, and translated these changes into French and Spanish.
- FHI updated the graphic design (in InDesign, rather than Excel).
- FHI printed 2000 laminated copies in three languages (6000 total) by June 30, 2006.

Findings and Outcomes:

- Findings from several systematic reviews led to changes in eligibility criteria for several contraceptive methods. These changes were published in the second (2004) edition of the "Selected Practice Recommendations for Contraceptive Use" and the third (2004) edition of the “Medical Eligibility Criteria for Contraceptive Use". These guidelines are available on the WHO Website, www.who.int/reproductive-health/publications.
- The WHO special consultation on progestin-only contraception and bone, made the following recommendations:
- There should be no restriction on the use of DMPA, including no restriction on duration of use, among women aged 18 to 45 who are otherwise eligible to use the method.
- Among adolescents (menarche to <18) and women over 45, the advantages of using DMPA generally outweigh the theoretical safety concerns regarding fracture risk. Since data are insufficient to determine if this is the case with long-term use among these age groups, the overall risks and benefits for continuing use of the method should be reconsidered over time with the individual user.
- Recommendations regarding DMPA use also pertain to use of NET-EN.
- There should be no restriction on the use of other progestogen-only contraceptive methods among women who are otherwise eligible to use these methods, including no restrictions on duration of use.
- There should be no restriction on the use of combined hormonal contraceptive methods among women who are otherwise eligible to use these methods, including no restrictions on duration of use.
- JHPIEGO requested permission to reprint the FHI MEC chart in a French Multi-method Family Planning document for Madagascar they are developing.

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/OYB	**FCO Approved:**	**2706**	Aug 2003
				112110	Jul 2005
				172003	Dec 2005
Total Approved Budget:	**2706**	$ 500,000	**Projected End Date:**		Aug 2007
	112110	$ 124,220			
	172003	$ 200,000			
		$ 824,220			

Worldwide: Cochrane Fertility Regulation Review Group, 2005-2010 (FCO 112112/172002)

Technical Monitor: DGrimes

Status: Ongoing
Group: CRD

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To perform systematic reviews and meta-analyses of randomized controlled trials on methods of family planning, with an early emphasis on IUDs and barrier methods.

Description: The Cochrane Collaboration is an international network of scientists and physicians conducting systematic reviews of medical evidence. A dangerous lag of over a decade exists between publication of life-saving research and its introduction into medical practice. Much of this utilization gap relates to the challenges in finding and absorbing the best available evidence about clinical practice. The Fertility Regulation Review Group, based in Leiden, the Netherlands, is coordinating a world-wide effort to identify, analyze, and disseminate in easily understood fashion the scientific evidence on family planning. The Cochrane systematic review process has several discrete steps that occur sequentially. The first is to register a title with the central office in Leiden. The next is to submit a protocol, which is a formal description of the methods to be used in searching and synthesizing the literature. This protocol is submitted to peer review and, after revision, is approved. The next step is to perform the actual review and write the report using Cochrane software (RevMan). The submitted review then undergoes external peer review and revision before its final acceptance. Once this is done, the review is published on the Cochrane Library (CLIB) CD-ROM. Cochrane reviews are also published in peer-reviewed journals.
This subproject represents COCHRANE research and review activities starting in October 2005. Previous activities were reported under the Cochrane Fertility Regulation Review Group, 1998-2005 subproject report.

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Activities, Accomplishments, Problems through December 31, 2005

- The following paper was revised and published: Lopez LM, Grimes DA, Schulz KF. Non-hormonal drugs for contraception in men: a systematic review. Obstet Gynecol Surv 2005; 60: 746-52 (FHI Pub #2005-60).
- The following protocol was submitted and revised: Grimes DA, Hubacher D, Lopez LM, Schulz KF. Non-steroidal anti-inflammatory drugs (NSAIDs) for heavy bleeding related to intrauterine devices.
- The following new titles were registered:
- 1) Newmann SJ, Grimes DA, Nanda K, Lopez LM, Schulz KF. Immediate start of combined hormonal contraceptives for contraception.
- 2) Lopez LM, Grimes DA, Schulz KF, Curtis K. Steroidal contraceptives: effect on bone fractures in women.
- 3) Combined oral contraceptives for functional ovarian cysts
- 4) Steroid hormones for contraception in women with sickle cell disease

- 5) Steroidal contraceptives: Effect on carbohydrate metabolism in women without diabetes
- The following content updates were completed:
- 1) Gallo MF, Grimes DA, Lopez LM, Schulz KF. Nonlatex versus latex male condoms for contraception.
- 2) Kuyoh MA, Toroitich-Ruto C, Grimes DA, Schulz KF, Gallo M, Lopez LM. Sponge versus diaphragm for contraception.
- 3) Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight.
- The following format updates were done:
- 1) Truitt ST, Fraser A, Gallo MF, Lopez LM, Grimes DA, Schulz KF. Combined hormonal versus nonhormonal progestin-only contraception in lactation.
- 2) Grimes DA, Lopez LM, Schulz KF, Stanwood N. Immediate postabortal insertion of intrauterine devices.
- 3) Grimes D, Schulz K, van Vliet H, Stanwood N, Lopez LM. Immediate post-partum insertion of intrauterine devices.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The following reviews were completed and scheduled for publication:
- 1) Grimes DA, Hubacher D, Lopez LM, Schulz KF. Non-steroidal anti-inflammatory drugs for heavy bleeding related to intrauterine devices.
- 2) Lopez LM, Grimes DA, Schulz KF, Curtis K. Steroidal contraceptives: effect on bone fractures in women.
- 3) van Vliet HAAM, Grimes DA, Lopez LM, Schulz KF, Helmerhorst FM. Triphasic versus monophasic oral contraceptives for contraception.
- 4) Grimes DA, Jones LB, Lopez LM, Schulz KF. Combined oral contraceptives for functional ovarian cysts
- The following review was developed and submitted: Lopez LM, Grimes DA, Schulz KF. Steroidal contraceptives: Effect on carbohydrate metabolism in women without diabetes
- The following review was revised and submitted: Cook LA, Pun A, van Vliet H, Gallo MF, Lopez LM. Scalpel versus no-scalpel incision for vasectomy.
- The following protocols were developed and submitted:
- 1) Newmann SJ, Grimes DA, Nanda K, Lopez LM, Schulz KF. Immediate start of combined hormonal contraceptives for contraception.
- 2) Manchikanti A, Grimes DA, Lopez LM, Schulz KF. Steroid hormones for contraception in women with sickle cell disease.
- The following reviews were updated with new searches, according to Cochrane policy:
- 1) Van Vliet HAAM, Grimes DA, Helmerhorst FM, Schulz KF. Biphasic versus monophasic oral contraceptives for contraception.
- 2) Van Vliet HAAM, Grimes DA, Helmerhorst FM, Schulz KF. Biphasic versus triphasic oral
- Handsearch – Staff updated the search of Contraception journal (Sept 2005 – February 2006) for trials to be included in the Cochrane Central Register of Controlled Trials.

Findings and Outcomes:

- A systematic review evaluated non-hormonal drugs given to men for contraception. In trials, gossypol had problems with efficacy and toxicity. In observational studies, sperm density was lower among men taking Tripterygium, but some toxicity was noted. We found no clinical studies for men with non-hormonal vaccines or neem. No comparative data were found for injecting styrene maleic anhydride into the vas deferens. No safe and effective non-hormonal drug is available for contraception in men.
- A systematic review summarized RCTs studying NSAIDs for treating bleeding or pain associated with IUD use. NSAIDs were effective in reducing pain and menstrual blood loss. NSAIDs should be first-line therapy; if ineffective, tranexamic acid may be considered. Prophylactic ibuprofen use with the first 6 menses after insertion appears unwarranted.

- A systematic review examined RCTs of OCs as therapy for functional ovarian cysts. Treatment with COCs did not hasten resolution - whether the cysts developed spontaneously or after ovulation induction. Although widely used for treating functional ovarian cysts, COCs appear to be of no benefit. Watchful waiting is appropriate. Should cysts persist, surgical management is often indicated.
- A systematic review evaluated using hormonal contraceptives before menopause on the risk of fracture. Combination contraceptives did not affect bone health. DMPA was associated with decreased bone mineral density. Whether steroidal contraceptives influence fracture risk cannot be determined from existing data. Health care providers and women should consider the costs and benefits of these contraceptives.
- A systematic review compared triphasic with monophasic OCs for efficacy, cycle control, and discontinuation. The triphasic and monophasic OCs did not differ in effect or discontinuation. Several trials had better bleeding patterns in triphasic OC users. The evidence is insufficient to determine if triphasic OCs differ from monophasic OCs in outcomes. We do not recommend triphasic pills as a first choice for women starting OC use. Large, high-quality RCTs that compare triphasic and monophasic OCs with identical progestogens are needed.

Funding Source(s):		USAID - US Agency for International Development/Core; USAID - US Agency for International Development/OYB	**FCO Approved:**	**112112** **172002**	Aug 2005 Sep 2005
Total Approved Budget:	**112112**	$ 380,000	**Projected End Date:**		Apr 2010
	172002	N/A			

Worldwide: Inter-Laboratory Trials (FCO 118104)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To conduct annual proficiency trials among accredited independent laboratories and condom manufacturers. This exercise helps ensure PQC's testing competence, and compliance with international laboratory performance standards.

Description: Inter-laboratory trials are key to establishing consistency and comparability among laboratories. Most, if not all, international procurement agencies depend on third-party laboratory testing to determine the acceptance of condoms prior to shipment. USAID and other procurement agencies use the results of these inter-laboratory trials to identify qualified laboratories. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Inter-laboratory trial test results were collected and statistically evaluated. A final report was issued to USAID in February.
- Twenty laboratories participated in the inter-laboratory trial in February 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: International Standards Development (FCO 118100)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: An ISO standard for synthetic male condoms and female condoms established

Objective(s): To actively participate in international standards organizations to establish new and/or revise existing performance standards for medical devices, pharmaceuticals, and other commodities procured and distributed by USAID.

Description: Product performance standards are required by regulatory agencies to ensure proper and consistent manufacturing and to protect consumers from harm. These internationally recognized consensus standards are used by USAID and other donor organizations when procuring products for developing country use. PQC will contribute its expertise and represent USAID's interests in the standards' community. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8010).

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Activities, Accomplishments, Problems through December 31, 2005

- Staff participated in the ISO TC Meeting in Berlin Germany, August 30 to September 10, 2006; the ASTM Meeting in Dallas, Texas, December 4-6, 2005; and the Female Condom Meeting in Baltimore, Maryland, September 26-29, 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Staff participated in a Female Condom Technical Review Meeting held at WHO (January 16-18, 2006), attended ISO Technical Committee meetings in Montreau, Switzerland (April 3-5, 2006) and ASTM D-11 meetings in Toronto, Canada (June 12-14, 2006).

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: Technical Assistance to Field Programs (FCO 118102)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide technical assistance to USAID field-funded programs and support field services initiatives through training and mentorship.

Description: Existing and potential contraceptive users must be assured that the products they receive are of good quality and will function as expected. Frequent use failure may discourage their acceptance and can jeopardize the sustainability of field programs. This subproject helps to ensure that the integrity of USAID-provided contraceptives and other commodities are adequately maintained during shipment and in-country storage. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8011).

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Activities, Accomplishments, Problems through December 31, 2005

- Technical officers from the Ugandan National Drug Authority (NDA) received three weeks of intensive training in laboratory set-up and management from the PQC staff in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Technical assistance was provided to the Medical Control Authority of Zimbabwe to assess product testing capability. As a result of the assessment, two technicians from MCAZ laboratory received two weeks of instruction from the PQC staff.
- Carter traveled to Uganda to provide assistance in training and set-up of the NDA Condom Testing facility (April 7-14, 2006).

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: Technical Leadership: Collaboration with Multi/Bi-Lateral Procurement Agencies (FCO 118101)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To improve donor procurement practices and develop appropriate product specifications for field programs.

Description: USAID fully supports collaborations among donor agencies. PQC routinely provides technical assistance in establishing procurement specifications, pre-qualification of potential suppliers, and handling field complaints. These and other activities will continue as appropriate under the CRTU. They are a continuation of activities conducted under the CTR (FCO 8010).

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Activities, Accomplishments, Problems through December 31, 2005

- There was no activity under the subproject during this timeframe.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: Technical Oversight Committee (FCO 118103)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To facilitate annual Technical Oversight Committee meetings to review PQC's program activities and strategies for the CRTU.

Description: The Technical Oversight Committee, established in 1995, is comprised of technical experts that monitor and advise PQC's program of work. Meetings are held annually, or

as needed, to ensure compliance with CRTU requirements. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

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Activities, Accomplishments, Problems through December 31, 2005

- There was no activity on this subproject during this timeframe. The November 2005 meeting was cancelled at the request of USAID.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The annual Technical Oversight Committee Meeting was held in March 2006 at the FHI/PQC office.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: Test Capability Development and Enhancement (FCO 118105)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To develop and/or enhance technical knowledge and test capability of products procured by USAID and collaborating agencies.

Description: PQC is in constant demand for technical assistance in addressing procurement and research product issues within FHI and from other CAs and donors. This sub-project will provide staff training, educational materials, and on-site experiences for select staff members. The activities conducted under this subproject are a continuation of activities conducted under the CTR (FCO 8015).

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Activities, Accomplishments, Problems through December 31, 2005

- As of December 2005, internal testing capabilities were developed for assessing the quality of microbicides prior to clinical trials. Test methods for SAVVY and PRO2000 have been acquired and adapted.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In early 2006, staff began developing internal capabilities to evaluate Sinoplant, Jadelle and Implanon Implants.
- David Jenkins attended the 2006 Microbicide Conference in Cape Town, South Africa in April.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

Worldwide: Production Surveillance, Domestic and Off-Shore, for Hormonal and Long-acting and Permanent Methods (FCO 148101)

Technical Monitor: ECarter

Status: Ongoing
Group: PQC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To ensure pre-distribution quality of hormonal methods and long-acting and permanent methods, procured domestically or offshore, for developing country programs.

Description: This program provides close scrutiny of both domestic and offshore production and ensures that a variety of hormonal and long-acting and permanent contraceptive methods produced by contracted factories meet USAID procurement specifications prior to distribution to field programs. One hundred percent of production lots are evaluated and factories are inspected periodically to ensure compliance with GMPs and USAID contract requirements. This subproject tracks payment for contracted sampling services and sample reimbursements. The activities conducted under this subproject are a continuation of domestic surveillance activities conducted under the CTR (FCO 8017); offshore surveillance began only under the CRTU.

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Activities, Accomplishments, Problems through December 31, 2005

- GMP/contract compliance audits were conducted at Pfizer/USA (DMPA) and Wyeth-Canada (Overette) in October 2005; findings were reported to USAID/CSL.
- A pre-qualification audit was conducted in December 2005, at Organon Pharmaceuticals (Oss, Netherlands). Organon, which manufactures 'Megestron' (DMPA), and which is being considered as an alternative supplier to USAID.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Staff continued to monitor production activities, evaluate product, and perform compliance audits when necessary or when requested.

Funding Source(s):	USAID - US Agency for International Development/Field Support	**FCO Approved:**	Jul 2005
Total Approved Budget:	$ 1,500,087	**Projected End Date:**	Apr 2010

USA: CTR End-of-Project & CRTU Project Launch Meeting (FCO 113120)

Technical Monitor: TOronoz

Status: Complete
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To disseminate the key findings of the CTR; 2) to encourage other USAID-supported programs, service delivery CAs and PVOs to pick up and adopt the lessons learned; and 3) to further the goals of coordination and collaboration under the CRTU.

Description: The main purpose of this meeting was to showcase CTR results and lessons learned so that others can apply them. In looking forward to the new CRTU, this meeting was also intended to foster the identification of opportunities whereby other CAs or PVOs, working independently or in partnership with FHI, could choose to scale up or replicate some of the key results of the CTR, as well as to partner on new efforts.

FHI held a one-day meeting on October 18, 2005 in Washington, DC to discuss CTR accomplishments and describe the major strategic goals and outcomes for the new CRTU. The agenda included welcoming remarks, a summary of the CTR: accomplishments and lessons learned, and an overview of the CRTU in the morning. Breakout sessions were held with the MoU partners in the afternoon.

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Activities, Accomplishments, Problems through December 31, 2005

- All logistical arrangements were finalized. Materials for the conference were prepared, and are reported, under another subproject (See 119501).
- The meeting was held at the Ronald Reagan Building on October 18, 2005.
- Approximately 110 people attended from USAID, MOU partners, other CAs and agencies.
- Minutes from the afternoon breakout sessions were emailed in December 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Approval to implement was obtained from USAID on January 10, 2006.
- The subproject was closed at the end of January 2006 as soon as all charges cleared.

Findings and Outcomes:

- Mihira Karra, GH/PRH/RTU reported that she had "a lot of positive feedback" on the meeting, as did FHI staff.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$ 100,000	**Projected End Date:**	Jan 2006

Multiple: Enhanced Country Program Implementation (FCO 113117)

Technical Monitor: TNutley

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in five focus countries; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in the focus countries.

Description: The enhanced country program (ECP), will be implemented in 4 priority countries, Kenya, South Africa, Uganda and Madagascar or Cambodia, defined as tier one countries. Activities in the tier one countries will facilitate the PH impact of the CRTU by leading the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, ECP will serve to identify and prioritize local research and program needs, develop and implement work plans that address those needs, foster collaborative partnerships, and facilitate the translation of research into practice.

The ECP will be grounded in the following activities: development and support of field presence through 2 existing offices (Kenya and South Africa, local costs for the South Africa office will be funded by another FCO) and the placement of 2 local staff in existing IHA or partner offices in Uganda and Madagascar or Cambodia; engagement of local stakeholders to guide research-to-practice efforts; needs assessment and prioritization to the development of a research and program agenda that meets needs at the country level; promotion/utilization of Best Practices; program and research project planning and management; monitoring and evaluation of work plans; management of the overall ECP approach; and mobilization/diversification of resources to sustain and expand ECP implementation.

A subset of the activities listed above will be conducted in a second tier of countries, Nigeria, Tanzania, India and Madagascar or Cambodia. It is envisioned that visits will be conducted to identify local stakeholders and RH experts.

A steering committee comprised of multidisciplinary FHI senior staff, will provide technical oversight to all ECP approaches and activities. Within each country, activities will be implemented

in collaboration with the MOH, local universities, the USAID Mission, MOU partners, other CAs as well as local NGOs, research firms, and community/advocacy groups.

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Activities, Accomplishments, Problems through December 31, 2005

- Staff developed a conceptual framework, a briefing sheet and an overview document.
- Subcommittees were formed to create a list of potential focus countries, develop a methodology to collect M&E country information and to identify RH priorities in focus countries.
- Negotiations on focus country status were held with Missions and local MOHs in Kenya, South Africa, Uganda, Tanzania, Mali, India and Pakistan.
- Meetings were held with MOU partners in Kenya and South Africa to introduce the CRTU.
- The Kenya stakeholder meeting was held in Naivasha, Kenya in November attended by five FHI staff and 18 representatives of other CAs and MOH. The meeting launched the CRTU, explained the role of the stakeholder group, outlined the potential role of the CRTU and generated a list of prioritized RH needs.
- In NC and Nairobi, meeting proceedings were distributed to staff and debriefing meetings were held.
- Six concept papers responding to prioritized needs identified at the Kenya Stakeholder Meeting were prepared and submitted for consideration in the year 2 CRTU workplan.
- MOU partners were contacted in Kenya to collect information on current activities related to the identified RH needs.
- An expedited needs assessment was developed for use in Mali and Uganda.
- Nairobi staff traveled to Mali and Uganda in Dec. 2005 to meet with USAID and stakeholders and to conduct the rapid assessment. Draft reports were prepared.
- Recruitment began for the Sr. Program Officer position in South Africa.
- Workplans and quarterly reports were prepared for USAID/Kenya and South Africa.
- TA was provided to NC staff to develop new projects and identify partners and project sites.
- Resource mobilization efforts were undertaken in Kenya and South Africa.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Country-specific research utilizations work plans were developed for Kenya, Uganda, South Africa and Madagascar to: assist in the identification of groups of results and products, specify activities to move the results/products into programs, identify partner involvement, identify country level indicators of success and ultimately, map each grouping back to CRTU strategies and outcomes.
- For CRTU marketing purposes with Francophone missions, the following documents were translated into French: Research Utilization: A Menu of Ideas for Collaborative Activities, CRTU brochure, USAID's Global Technical Brief: Checklists Reduce Medical Barriers to Contraceptive Use, Integrating FP and VCT in Kenya Fact Sheet, Preparedness of VCT Centers in Kenya to provide FP, Mali RH Rapid Assessment.
- Multiple conversations were held with USAID/Mali to assess their interest in the CRTU. The mission declined CRTU assistance citing that they currently have sufficient technical assistance organizations working on FP in Mali. They requested information on integrating VCT and FP, which was provided.
- NC staff participated in the South Africa Stakeholders meeting. Proceedings were drafted and shared with staff.
- Kenya and South Africa Project Directors traveled to NC in June to report on the status of the FCP in their countries, share local RH needs, and develop country-specific project ideas for the year 3 work plan.
- Recruitment began for the Project Director in Uganda. In June 2006, NC staff traveled to Uganda to interview two candidates for the position, negotiate office space with the local bilateral and investigate possible collaborative activities with partners.

- Conversations were held with SanteNet, the Madagascar bilateral, to follow-up on the findings of the Best Practices Country Assessment (FCO 113115). A draft implementation plan was prepared.
- Work plans and quarterly reports were prepared for USAID/Kenya and South Africa.

Findings and Outcomes:

- During the first year of the CRTU, stakeholders identified RH priorities through stakeholder meetings in Kenya, Uganda and South Africa during November 2005, December 2005 and March 2006, respectively. Also, the Best Practices Assessment team met with several key stakeholders to identify RH priorities in Madagascar during the March-April 2005 assessment visit. Full reports of meeting proceedings and findings are available for each country. Common themes and RH needs/challenges identified across countries include:
- HIV and Contraception
- Generate information to refine models of integration and evaluate impact of innovative integration models.
- Improve dissemination of evidence and knowledge on FP and HIV integration to inform policymakers and program managers.
- LAPMs
- Increase demand by addressing misinformation and improving attitudes of both clients and providers.
- Strengthen providers' skills and confidence.
- Identify, investigate and support efforts to improve access by expanding the types of providers (i.e. nurses, clinical officers) delivering LAPM services.
- Hormonal Methods
- Expand access by increasing service delivery points (i.e. pharmacies, CBD of DMPA).
- Improve providers' attitudes, skills and confidence to provide hormonal methods.
- All Methods / Cross-Cutting
- Update, harmonize and improve dissemination of RH policies and guidelines.
- Increase providers' efficiency and improve counseling skills on sexuality and the full range of contraceptive methods.
- Expand male and youth involvement in RH and strengthen RH services for these populations.
- Support advocacy efforts to reach opinion leaders and policymakers with FP/RH information to mobilize resources for FP programs and contraceptive commodities.
- Enhance information, education and communication (IEC) to increase demand for and to augment the capacity of providers to offer quality FP/RH services.

Funding Source(s):		USAID - US Agency for International Development/Core	**FCO Approved:**	Sep 2005
Total Approved Budget:	$	8,706,661	**Projected End Date:**	Apr 2010

Kenya: Enhanced Country Program Implementation (FCO 113122)

Technical Monitor: MKuyoh
Collaborating Agency(s): Management Sciences for Health (MSH); Population Council; PATH; Johns Hopkins/CCP; EngenderHealth; Adventist Development Relief Association (ADRA)

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in Kenya; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in Kenya.

Description: The enhanced country program (ECP), which will be implemented in four priority countries including Kenya, will facilitate the public health impact of the CRTU by leading to the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the enhanced country program will serve to identify and prioritize local research and program needs, develop and implement country workplans that address those needs, foster collaborative partnerships with local groups, and facilitate the translation of research into practice. The program in Kenya will be grounded in the following core activities:
Creating and supporting a CRTU Stakeholder Committee composed of CRTU memorandum of understanding (MOU) partners, RH/HIV/AIDS NGOs, USAID cooperating agencies, local universities and professional organizations, the MOH, and USAID Mission staff to identify and prioritize country RH needs.
Convening partners to assist in developing research and program agendas that meet country level needs, identify opportunities for collaboration and joint work planning, identify approaches to improve policies and programs and scale-up programs improved by FHI research.
Promoting and utilizing existing RH research results and USAID Best Practices.
Providing assistance with program and research planning and development, and project oversight.
Developing and monitoring country workplans.
Supporting local staff salaries and costs associated with office infrastructure.
Mobilizing and diversifying resources to sustain and expand country level activities.
A steering committee comprised of multidisciplinary FHI senior staff will provide technical oversight to all ECP approaches and activities. Within each focus country, activities will be implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperating agencies as well as local NGOs, research firms, and community/advocacy groups.

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Activities, Accomplishments, Problems through December 31, 2005

- FHI obtained approval from USAID/Kenya to include Kenya as a CRTU focus country.
- Approval to implement the Kenya program was included in the overall Enhanced Country Program and other CRTU focus counties.
- In October, discussions were held with partners in Kenya to introduce the CRTU and invite their involvement in the CRTU Stakeholder Committee.

- Staff members prepared for the first CRTU Stakeholder Committee and Partners Council meetings. The meeting agenda, presentations, breakout group discussion guides, needs identification matrix, facilitator guidance and prioritization process were developed. Also, Stakeholder Committee members were identified, including CRTU MOU partners, RH NGOs, CAs, local universities, professional associations, the MOH and USAID.
- In November, nearly 30 stakeholders representing a cross section of the RH community in Kenya participated in a 1.5 day meeting in Naivasha. The meeting launched the CRTU, explained the role and expectations of the stakeholder group, outlined the potential role of the CRTU in Kenya and generated a list of 13 prioritized RH needs.
- Proceedings from the stakeholder meeting were prepared and distributed and debriefing meetings were held.
- The baseline information gathering was initiated and background information was collected on the current state of RH and FP programs in Kenya (with co-funding from FCO 119501). A consultant was identified to work in collaboration with the CRTU M&E unit in NC to provide in-country expertise for the assessment.
- MOU partners were contacted to collect information on current activities as they related to the identified list of RH needs. A matrix was completed to organize this information.
- The Kenya Project Director provided TA to Uganda during the initial stakeholder meeting to introduce the CRTU and identify priority issues that can be included in the second year CRTU work plan.
- The initiation and continued implementation of CRTU subprojects in Kenya was supported.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In March 2006, concept papers were submitted to the USAID Mission in Kenya to solicit FY07 population field support funding.
- Baseline information on Kenya was collected and the Kenya CRTU baseline assessment report was finalized in May 2006 (funded by 119501).
- Information on MOU partners' activities was collected and compiled into a comprehensive matrix. This information was disseminated to staff in order to explore collaborative opportunities in Kenya and inform FHI staff's concept proposal development.
- The Kenya Project Director met regularly with MOU partners to foster collaborative work planning.
- Potential collaborative opportunities were identified with Partners Council members (MOU partners, MOH and USAID). These ideas for collaboration address both RH priorities identified at the CRTU stakeholder meeting and the CRTU global agenda.
- The Project Director visited North Carolina to foster collaboration with HQ staff and strengthen management systems to support the Nairobi office.
- Quarterly program updates were prepared for USAID/Kenya.
- Field Programs staff continued to assist staff in other divisions to develop new projects and identify appropriate partners and project sites in Kenya.
- Resource mobilization activities in Kenya continued (funded by FCO 1118).
- A comprehensive matrix summarizing CRTU activities in Kenya, including results/products, partners and outcomes/indicators was prepared and presented to USAID/Washington.

Findings and Outcomes:

- The RH priorities identified by stakeholders in Kenya and the CRTU strategy topic associated with each priority area are as follows:
- 1. LAPMs and HC: Increase providers attitudes, skills and confidence to provide LAPMs and HC.
- 2. LAPMs: create demand (decrease myths, address side effects, improve image).
- 3. Barrier methods: Scale-up and evaluate community based distribution through non-health networks (ex. via agriculture workers).
- 4. All methods: Target opinion leaders/policy makers with advocacy messages so they can support/lobby for FP.

- 5. All methods: Involve men and youth (ex: mobile video units with messages targeted to these populations to increase demand).
- 6. Contraception & HIV: Generate strategic information to continue to refine models of integration.
- 7. Contraception & HIV: Improve knowledge of the relationship of contraception & HIV; inform policy with this information.
- 8. Barrier methods: Improve provider skills to communicate messages on sexuality.
- 9. All methods: Promote best practices that increase provider efficiency (ex. Population Council's balanced counseling strategy).
- 10. Contraception & HIV: Improve models of supervision and other programmatic inputs.
- 11. Hormonals: Increase access through increasing service delivery points (CBD-depo, pharmacists, etc.).
- 12. LAPMs: Expand types of providers that provide LAPMs (nurse provision of mini-lap etc.).
- 13. All methods: Harmonize and disseminate policies; ensure adherence.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Oct 2005
Total Approved Budget:	Annually Approved	**Projected End Date:**	Apr 2010

South Africa: Enhanced Country Program Implementation (FCO 113123/133100)

Technical Monitor: ECanoutas

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To identify and prioritize local reproductive health research and program needs in South Africa, as one of five focus countries under the CRTU; and 2) to facilitate efficient, effective implementation and utilization of reproductive health research and programs in South Africa.

Description: The enhanced country program, which will be implemented in five priority countries, including South Africa, will facilitate the public health impact of the CRTU by leading the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the enhanced country program will serve to identify and prioritize local research and program needs, develop and implement country work plans that address those needs, foster collaborative partnerships with local groups, and translate research into practice. The enhanced country program in South Africa will be grounded in the following core activities: support of field presence in the existing South Africa field office; engagement of local stakeholders to oversee research-to-practice efforts; country needs assessment and prioritization to inform the development of a research and program agenda that meets needs at the country level; promotion and utilization of USAID Best Practices; program and research project planning and management oversight; monitoring and evaluation of country work plans; management of the overall enhanced country program approach; and mobilization and diversification of resources to sustain and

expand enhanced country program implementation. A steering committee composed of FHI senior management, and staff from participating divisions will provide technical oversight to the focus country program approach and activities. In South Africa, activities will be implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperative agencies as well as local NGOs, research firms, and community and advocacy groups.
Note: For Year Two, this activity will be funded out of microbicides funds budgeted under: "Phase IIb Trial – Savvy vs. Tenofovir Gel," and "Next Steps for Clinical Research of New FCs".

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Activities, Accomplishments, Problems through December 31, 2005

- In October 2005, the Deputy Director of Field Programs and South Africa Project Director (PD) met with the USAID Mission in South Africa to secure buy-in for the enhanced country program. The mission expressed their support for the CRTU objectives and urged FHI to focus specifically on the integration of Reproductive Health and HIV/AIDS programs in South Africa.
- A search was begun for a new Senior Program Officer to support the enhanced country program.
- With funding from FCO 119501, FHI NC staff began a desk review of the current reproductive health situation in South Africa to inform both the baseline assessment for the M&E process as well as future proposal development.
- In preparation for a stakeholders' meeting in March 2006, the South Africa PD initiated contact with MOU partners to review CRTU goals and objectives.
- The South Africa PD and the FHI/NC South Africa Country Monitor prepared and monitored the office operating budget; reviewed financial reports; developed and submitted the 2006 PEPFAR Country Operational Plan; provided TA on new project development in SA by helping FHI staff to identify collaborating partners and geographic project and study focus; and coordinated activities with the FHI Institute for HIV/AIDS.
- The semiannual PEPFAR activity report was prepared and submitted to USAID in November 2005.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The new Program Officer will begin her contract in August 2006. Based on available candidates, the PD downgraded the position to a Program Officer and thereafter completed the hiring process.
- Additional information regarding the status of RH in South Africa was collected for the M&E baseline. The document was completed in June 2006 with funding from FCO 119501.
- FHI held a CRTU stakeholders meeting in Pretoria in March 2005. Staff from the DOH, CRTU MOU CAs, and other key RH organizations convened for a one-day meeting focusing on the integration of RH and HIV/AIDS programs. The meeting objectives were to launch the SA CRTU stakeholder committee; introduce the CRTU to the committee; identify and prioritize challenges and needs related to RH/HIV integration; and develop strategies to address those challenges and needs.
- The PD followed up with the stakeholders to further explore the group's findings and identify areas for collaboration (see findings section below). The stakeholders will meet annually, or as need arises, to discuss new RH needs, additional opportunities for collaboration under the CRTU, and the potential application of new evidence that can be applied in their programs.
- The semiannual PEPFAR activity report was prepared and submitted to USAID in April 2006.
- The PD and the FHI/NC TM monitored the office operating budget; reviewed financial reports; developed and submitted ideas for the 2007 PEPFAR Country Operational Plan; provided TA on new study development in SA by helping FHI staff to identify collaborating partners and geographic project and study focus; and coordinated activities with the FHI Institute for HIV/AIDS.
- The PD traveled to headquarters to present FHI/SA activities to staff; report on enhanced country program progress and pitch ideas for collaboration with local stakeholders; meet with

department directors to review capacity to respond to needs in country; and attend a training course on project management and supervision.

Findings and Outcomes:

- In December 2005, the USAID Mission agreed to the inclusion of South Africa as a CRTU focus country.
- Participants in the stakeholders meeting in March 2006 identified the following as priorities in the area of FP/HIV integration in South Africa:
- Lack of support and understanding among management staff regarding FP/RH and HIV/AIDS service integration;
- Lack of information on innovative models for integration and monitoring impact;
- Vertical or separate programming and lack of a multi-sectoral and holistic approach to provision of RH and HIV services and programs;
- Training manuals, policies and service delivery guidelines not updated regularly and standardized based on new evidence to implement integration; and
- Poor service provider skills to provide appropriate counseling on FP.
- In follow-on meetings between FHI's PD and the stakeholders, several research and program ideas were discussed as potential collaboration opportunities, including:
- Does the integration of RH services into HIV/AIDS services impact positively on health outcomes such as reduction in MTCT/maternal mortality and morbidity, and vice versa? (Partner: RHRU)
- Does improved counseling about RH information at ARV sites improve women's uptake of RH services? (Partner: RHRU)
- How can VCT be successfully integrated into existing busy family planning scenarios? (Partner: RHRU)
- Identify and compile current models of FP/HIV integrated programs in South Africa. Disseminate information from these models locally and regionally. (Partner: NDOH)
- Review the NDOH SRH curriculum and revise it to include information on contraception for women who are HIV-positive, and those on ARVs. (Partner: NDOH)
- Support an "integration champion" in the NDOH to help establish evidence-based policies, training curricula, and programs related to FP/HIV integration. Provincial DOH champions would also be identified and supported. (Partner: NDOH)
- The PD and the SA Country Monitor are exploring these opportunities, including potential funding sources, with staff in North Carolina and in the field.

Funding Source(s):	USAID - US Agency for International Development/Core; USAID - US Agency for International Development/Microbicides		**FCO Approved: 113123** **133100**	Oct 2005 Jul 2006
Total Approved Budget: 113123 **133100**	Annually Approved	$ 768,620	**Projected End Date:**	Apr 2010

Uganda: Enhanced Country Program (FCO 113125)

Technical Monitor: KKrueger

Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): To provide the infrastructure through which CRTU outcomes and public health impact will be attained in Uganda.

Description: The enhanced country program, which will be implemented in five priority countries, including Uganda, will facilitate the public health impact of the CRTU by leading the prioritization, implementation and utilization of research to inform local policies and programs. More specifically, the enhanced country program will serve to identify and prioritize local research and program needs, develop and implement country workplans that address those needs, foster collaborative partnerships with local groups, and translate research into practice.
The enhanced country program in Uganda will be grounded in the following core activities: start-up and support of the Uganda country office and field staff; engagement of local stakeholders to oversee research-to-practice efforts; country needs assessment and prioritization to inform the development of a research and program agenda that meets needs at the country level; promotion and utilization of USAID Best Practices; program and research project planning and management oversight; monitoring and evaluation of country workplans; management of the overall enhanced country program approach; and mobilization and diversification of resources to sustain and expand enhanced country program implementation. A steering committee composed of FHI senior management, and staff from participating divisions will provide technical oversight to the focus country program approach and activities. In Uganda, activities will be implemented in collaboration with the Ministry of Health, local universities, the USAID Mission, MOU partners, other cooperating agencies as well as local NGOs, research firms, and community and advocacy groups.

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Activities, Accomplishments, Problems through December 31, 2005

- In October 2005, the Director of Field Programs met with the USAID Mission in Uganda to secure buy-in for the Focus Country Program.
- USAID-Uganda concurrence for the Focus Country Program was given in November 2006.
- In December 2006, a stakeholders' meeting was held to introduce partners to the CRTU and focus country program and to conduct a rapid assessment to generate reproductive health research priorities for the country.
- The assessment report was written and disseminated in February 2006.
- In February 2006, a meeting was held with MOU partners and other members of the MOH RH working group to debrief on the assessment findings and to develop a partners' collaboration matrix outlining current work conducted within the priorities generated in the December stakeholders' meeting.
- In March 2006, a search was begun for a Program Director to manage the Focus Country Program in Uganda.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- In January 2006, the Stakeholders' CRTU Launch Meeting Report was drafted, finalized, and shared with FHI staff highlighting the RH priorities identified during the December 2005 meeting.
- A development strategy was created for launching the FCP in Uganda.
- A position description for the Project Director was developed and shared with relevant partners for input in January 2006.
- A comprehensive budget was finalized for the Uganda FCP in February 2006.
- In February 2006, MOU partners were targeted for participation at the FP working group meeting hosted by the MOH to review the findings of the December priorities meeting and introduce the CRTU partner collaboration matrix exercise to further understand the programmatic portfolios of MOU partners.
- The USAID Mission requested that FHI continue to support the Uganda FP working group meetings for the coming year.
- MOU partners completed the matrix exercise and FHI compiled the results in March. It was determined that additional in-person meetings would be beneficial to further define ways in which FHI might compliment the programmatic activities of MOU partners.
- In March 2006, an in-house meeting was held with all FHI staff currently working in Uganda to coordinate efforts and reporting.
- FHI's M&E Unit developed the CRTU Uganda Baseline report (Feb-June).
- Recruitment for the Project Director position began in April 2006. Final candidates were selected in May.
- In June 2006, the Technical Monitor traveled to Uganda to conduct interviews for the Project Director position, negotiate office space and infrastructure with a local partner, and meet with USAID and MOU partners regarding FHI's current portfolio and future opportunities.
- In June, a results matrix was developed for the Uganda FCP under the CRTU.
- The USAID/DC monitoring visit was postponed from June to October to ensure the Project Director is hired and prepared for the visit.

Findings and Outcomes:

- In November 2005, the USAID Mission agreed to the inclusion of Uganda as a CRTU focus country.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Apr 2006
Total Approved Budget:	$ 1,023,490	**Projected End Date:**	Apr 2010

Worldwide: CRTU Monitoring and Evaluation (FCO 119501)

Technical Monitor: SMcIntyre

Status: Ongoing
Group: EXEC

USAID Intermediate Outcome: IR1 = Improved and New Contraceptive and Reproductive Health Technologies Developed, Evaluated and Approved.
IR2 = Microbicides and Microbicides/Spermicides Developed, Evaluated and Approved.
IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To monitor performance in CRTU-related subproject efforts; 2) to share results promptly to guide subsequent efforts and decision-making; 3) to assess progress toward the achievement of intermediate results; and 4) to evaluate the extent to which CRTU goals and objectives have been met and have had demonstrable impact.

Description: FHI will regularly assess the CRTU program and its subprojects performance through routine monitoring. This will keep FHI and USAID management, as well as other stakeholders, informed of progress. Monitoring will also be used to alert management of the need to adjust plans. Each subproject will have an assigned manager charged with meeting subproject objectives and completing the subproject on time and within budget. The M&E staff will focus on the measurement and tracking of outputs, outcomes, and the overall impact of the CRTU program. Country offices, and program officers for countries where there is no office, will play a role in gathering country-specific information needed to assess progress toward desired outcomes and impact. This information might include revisions to national guidelines, or trend data on the use of contraceptive or STI prevention technologies.
FHI will also undertake an evaluation to assess the research-to-practice process. Baseline measurements will be sought for key indicators from priority or focus countries where FHI anticipates a substantial number of activities. These baseline measurements will include selected indicators already available through national family planning or reproductive health programs, DHS data, or other organizations' reports.

2005—06 ANNUAL REPORT

Activities, Accomplishments, Problems through December 31, 2005

- A series of briefs outlining the accomplishments and impact of work done under the CTR Program was produced, completing work begun under the CTR (FCO 9993). Topics covered were: the IUD, female condom, vasectomy, hormonal contraception, male barrier methods, research methodology, information dissemination, and HIV and contraceptive services. All other briefs were completed in time for the end of the CTR/CRTU Project Launch Meeting, held in Washington, DC on October 18, 2005. The series was included in the packets provided to all participants.
- At this same meeting, Jason Smith and Susan McIntyre gave a joint presentation on the accomplishments and lessons learned under the CTR.
- A "gap analysis" was completed of the first CRTU Workplan, whereby proposed CRTU outcomes not currently being addressed by any CRTU subproject were identified. This analysis then helped to inform the development of the 2006-07 Workplan.
- A desk review was begun to inform baseline assessments for Kenya and South Africa. Some of the information thus obtained was used in preparing for the first Kenya Stakeholders' meeting of the CRTU.
- A new associate program officer began work in mid-December; the majority of her time is dedicated to M&E activities.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- The CRTU baseline assessment for Kenya was completed and distributed in June. Those for South Africa and Uganda were largely completed and will be distibuted in early July.
- The "gap analysis" of CRTU's on-going subprojects tracked to goals and outcomes was updated with notations as to goals and outcomes determined to be of lower priority to USAID. New and second year subprojects were also added into the analysis.
- A model format for a "success story" of CRTU activity was developed.
- Meetings were held with staff of FITS and HSR to familiarize them with the monitoring and evaluation plans under the CRTU and to solicit their input on future success stories and other M&E reporting.

- The M&E unit worked with field program staff to develop country matrices for Kenya, South Africa and Uganda, outlining outputs and research indicators to be addressed.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	N/A	**Projected End Date:**	Apr 2010

Kenya: Kenya Division of Reproductive Health Capacity Development: Follow-on Activity (FCO 143103)

Technical Monitor: CToroitich-Ruto
Collaborating Agency(s): Population Council; Ministry of Health, Kenya; EngenderHealth; Measure Evaluation
Status: Ongoing
Group: FITS

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Strategy Outcome: As a cross-cutting activity, this subproject facilitates the translation of research results into practice by working across strategic areas of work.

Objective(s): 1) To enhance Kenya's Division of Reproductive Health (DRH) staff capacity at all levels in research management and data utilization for decision-making skills to ensure research utilization and evidence-based programming; 2) to provide a clear system and set of guidelines for conducting RH research in Kenya; 3) to provide efficient communications between the DRH (all levels) and partners as facilitated by establishing a DRH Web site; and 4) to provide a platform for gathering strategic information and evaluating public health impact through the annotated bibliography on the Web site and the existing resource center.

Description: The MOH, DRH has clearly expressed growing concern over the current inability to identify, participate in, and coordinate RH research conducted in the country which has resulted in duplication, missed opportunities, and disregard for national RH priorities. As a consequence, a systematic pathway for identifying, prioritizing, and utilizing research findings and results in RH programs faces significant obstacles. FHI has been assisting the DRH to build its capacity in order to coordinate and make relevant data more readily available to policy makers, program managers, researchers, and individuals. This follow-on activity will build upon the accomplishments of the previous subproject (FCO 3444) by enhancing and scaling-up several ongoing components such as finalizing research management guidelines, roll-out and evaluation of research management and data-for-decision-making trainings, and enhancements to the DRH Web site. All of these activities enhance Kenya's ability to build and improve public health by refining national systems, upgrading skills set, and building infrastructure at the national, provincial, and district levels.
The previous subproject has been implemented with collaboration from UNFPA, WHO, DfID, and MEASURE Evaluation.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- FHI Staff:
- Completed the Approval to Implement letter and finalized the RY06 work plan in December 2005.
- Edited and designed research guidelines.
- Organized and conducted two Data for Decision-Making training sessions in Coast (May 2006) and Western (June 2006) Provinces.
- Organized the RH research management training.
- Interviewed for the Web writer and Web designer.

Findings and Outcomes:

- The DRH Resource center staff have been referring students from the Kenya Medical Training College and the University of Nairobi Medical School to the Web site. Some in-country collaborating agencies such as the Africa Population Health and Research Center have derived information on CAs collaborating with the DRH in Kenya, from the Web site.
- The National Co-ordinating Agency for Population and Development has visited the DRH to seek technical advice on how to set up their own Web site. Plans are underway in setting this up.
- The Kenya Expanded Program for Immunization is also planning to establish a Web site but is looking for funding.
- DRH has taken a big step in improving research utilization by re-establishing a research working group to help them strengthen the management and utilization of RH data throughout the country. The working group is part of a larger capacity-building project that is receiving technical assistance from FHI and partners to develop tools, trainings, and systems to help policy-makers, program managers, and researchers more easily access and utilize evidence-based information. The working group which is under the leadership of the DRH, is composed of 16 member organizations, including national and international organizations. The group met for the first time in February 2006 in Nairobi to outline its responsibilities. These include advising the MOH on the latest evidence that can improve RH services, facilitating partnerships and research utilization among local research agencies, and advocating adoption of research-based reproductive health policies, among others.

Funding Source(s):	USAID - US Agency for International Development/Field Support	**FCO Approved:**	Dec 2005
Total Approved Budget:	$ 212,499	**Projected End Date:**	Jun 2007

In the course of implementing the CRTU program, FHI is called upon to provide external agencies with support that facilitate the achievement of program goals. While technical assistance (TA) is provided to numerous organizations through implementation of work under the CRTU strategy areas, technical support activities represent systematic support that may extend across the life of the cooperative agreement (e.g. Coordination of CONRAD Activities and Regulatory Affairs and Quality Assurance) or which may arise at the request of the sponsoring agency and/or USAID (e.g. WHO Technical Assistance). As such, these initiatives are separated from other more programmatic technical support efforts.

TECHNICAL SUPPORT

FHI/NC subprojects fully or partially funded by USAID's CRTU Agreement:

USA:	Coordination and Statistical Support of CONRAD Activities (FCO 112100)
USA:	Regulatory Affairs and Quality Assurance for the CRTU (FCO 119200)
Switzerland:	WHO Technical Assistance – Sarah Johnson (FCO 119505)
Switzerland:	WHO Technical Assistance – Shawn Malarcher (FCO 114112)
USA:	Microbicide Database, Phase I, Social & Scientific Systems, Inc. (SSS) (FCO 139500)
USA:	Cost-Effectiveness Analysis of Assisted Reproductive Technology (FCO 174001)
Worldwide:	Information Resources Services (FCO 760/1067/119500)

USA: Coordination and Statistical Support of CONRAD Activities (FCO 112100)

Technical Monitor: LGlover
Collaborating Agency(s): CONRAD
Status: Ongoing
Group: CRD

Objective(s): To provide general management and statistical support of CONRAD-sponsored activities that are supported by FHI staff.

Description: The number of studies on which FHI and CONRAD collaborate has increased dramatically and now involve staff from several FHI divisions (Biostatistics, Data Management, Clinical Research, Behavioral and Social Sciences, and Regulatory Affairs and Quality Assurance). Oversight of these joint activities needs to be centralized to make their implementation more efficient. In addition, general statistical support by Biostatistics staff for CONRAD's USAID-supported work that does not have its own FCO will be provided via this subproject.

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Activities, Accomplishments, Problems through December 31, 2005

- A Quarterly Meeting was held August 30, 2005, at CONRAD's Arlington, Virginia, office. Fifteen representatives from CONRAD, FHI, and USAID participated in the all-day meeting.
- A SharePoint website was created for access by both FHI and CONRAD staff. Its purpose is to facilitate communication between the two organizations on their collaborative work.
- A Quarterly Meeting was held November 29, 2005, at FHI's North Carolina office. Twelve representatives from CONRAD, FHI, and USAID participated in the all-day meeting.
- General coordination and oversight for 24 subprojects was provided during the July 2005-June 2006.
- General statistical consultation was provided to clinicians at CONRAD.
- Guidelines on confidentiality were established for managing the subprojects within the collaboration.
- Progress toward milestones and enrollment statistics were tracked for all the collaborative studies.
- Frequent telephone conversations were held with CONRAD management staff to facilitate the implementation of the activities, and to provide input to FHI's workplans being developed for submission to USAID.
- Summary reports on the collaborative activities were prepared for use by FHI staff and by CONRAD management.

Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- A Quarterly Meeting was held February 28, 2006, at CONRAD's Arlington, Virginia, office. Ten representatives from CONRAD, FHI, and USAID participated in the all-day meeting.
- Training on the Confidentiality Guidelines was provided for staff working on collaborative subprojects.
- An Implementation Plan for the MoU Partnership between FHI and CONRAD was drafted in April 2006.
- A Quarterly Meeting was held May 30, 2006, at FHI's North Carolina office. Eleven representatives from CONRAD, FHI, and USAID participated in the all-day meeting.
- An FHI SOP, applicable to all studies under the collaboration, was finalized and implemented in June 2006.
- Training on the SOP was conducted for staff working on collaborative subprojects.
- Progress Reports for the FHI-CONRAD MoU Partnership were created.

- Biostatistics staff provided answers to follow-up questions from CONRAD clinicians for closed studies supported by USAID, in particular (1) CS Cameroon (study #9766/FCO 2272) and (2) SILCS PCT (study #9797/FCO 2281).
- The manuscript for the closed Microbicide Placebo study, supported by USAID (study #9820/FCO 2280), was reviewed by the study biostatistician.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Jul 2005
Total Approved Budget:	N/A	**Projected End Date:**	Jun 2007

USA: Regulatory Affairs and Quality Assurance for the CRTU (FCO 119200)

Technical Monitor: JRobinson

Status: Ongoing
Group: RAQA

Objective(s): To provide Regulatory Affairs and Quality Assurance suppport to CRTU subprojects

Description: This subproject covers costs associated with FHI's regulatory support for the Contraceptive Technology and Family Planning Research Program. A number of RA/QA activities are funded and reported as part of the specific studies; this subproject supports more general and short-term CRTU-related efforts, including RA/QA representation on a number of CRTU project teams to provide regulatory and quality assurance guidance. It also supports a portion of the RA/QA work related to the continued enhancement of the serious adverse event reporting, tracking of institutional review board approval, and study files systems used to support the CRTU as well as other Programs.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Routine regulatory and quality assurance support has continued to be provided to CRTU studies. A number of RA/QA activities are funded and reported as part of the specific studies.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Oct 2005
Total Approved Budget:	$ 100,000	**Projected End Date:**	Apr 2010

Switzerland: WHO Technical Assistance - Sarah Johnson (FCO 119505)

Technical Monitor: SMcCarthy

Status: Ongoing
Group: EXEC

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): To facilitate the development of evidence-based family planning guidance in the WHO Department of Reproductive Health and Research (RHR).

Description: Family Health International and the World Health Organization have reviewed measures to strengthen their scientific and technical co-operation in the field of research in human reproduction within the Organizations' programs. This subproject will facilitate this cooperation. A contracted FHI staff person will be assigned to work with the WHO Department of Reproductive Health and Research.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- Sarah Johnson was identified for the position and her contract was negotiated as of July 1, 2006.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	May 2006
Total Approved Budget:	$ 150,704	**Projected End Date:**	Jul 2007

Switzerland: WHO Technical Assistance - Shawn Malarcher (FCO 114112)

Technical Monitor: KKatz

Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): To provide social science assistance to the Reproductive Health and Research (RHR) Department within WHO.

Description: This subproject provides support for a technical assistant to work with the Strategic Component of Social Science Research on Reproductive Health, WHO, to implement and manage the social science research program. The technical assistant monitors research initiatives, conducts subproject reviews for policy and program implications, and prepares project summaries. The technical assistant also participates in preparations for the Scientific Review Committee, provides technical assistance to projects, reviews policy implications of research,

prepares synthesis reports highlighting major research results and resultant policy implications, and assists with dissemination of program and policy recommendations.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- This subproject was opened in April 2006, and approval to implement was received in May.
- Shawn Malarcher was hired in April 2006 and relocated to Geneva in May. She commenced her duties at WHO upon arrival.
- Throughout May and June, Shawn reviewed protocols and briefs. She also attended the YouthNet meeting on youth in Tanzania.

Funding Source(s):	USAID - US Agency for International Development/Core	**FCO Approved:**	Apr 2006
Total Approved Budget:	$ 250,412	**Projected End Date:**	Apr 2008

USA: Microbicide Database, Phase I, Social & Scientific Systems, Inc. (SSS) (FCO 139500)

Technical Monitor: CDreisbach

Status: Ongoing
Group: EXEC

Objective(s): To provide support to SSS in the development of a database and reporting system for monitoring and evaluating USAID-supported microbicide research and development activities.

Description: FHI has been asked by USAID to provide funding to Social & Scientific Systems, Inc (SSS) for the development of a programmatic database and reporting system for USAID's microbicide portfolio. SSS initiated work on this effort under the Synergy Project. That project officially ended January 31, 2006.

Given that SSS had not yet completed work on the database system, USAID requested that FHI provide funding - throught its Contraceptive and Reproductive Health Technologies Research and Utilization Program (CRTU) cooperative agreement - to SSS for the period of February 1 - June 30, 2006. This was to allow SSS to complete the first phase of their development of this system, during which the "USAID Microbicide Portfolio System" will be finalized and tested. In addition, SSS staff provided assistance with training, deployment and documentation.

A no-cost extension through July 15, 2006 has been granted to SSS, Inc. to complete the first phase activities.

In June 2006, USAID requested a cost-extension of the contract through December 31, 2006 to fund follow-on activities to this subproject. These include training stakeholders and collecting, analyzing and reporting the first round of base-year data on USAID-supported Microbicides R & D. SSS, Inc. will also perform IT-related activities to transfer the functional database from SSS to AIM.

FHI is to be reimbursed by USAID for the costs incurred in funding and monitoring SSS's cost reimbursement subcontract.

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Activities, Accomplishments, Problems through December 31, 2005

- A no-cost extension through July 15, 2006 has been granted to SSS, Inc. to complete the first phase activities.
- In June 2006, USAID requested a cost-extension of the contract through December 31, 2006 to fund follow-on activities to this subproject. (These include training stakeholders and collecting, analyzing and reporting the first round of base-year data on USAID-supported Microbicides R & D. SSS, Inc. will also perform IT-related activities to transfer the functional database from SSS to AIM.)
- Stakeholder training began August 30, 2006, and data entry commenced September 2006.

Funding Source(s):	USAID - US Agency for International Development/CSL-Core	**FCO Approved:**	Feb 2006
Total Approved Budget:	In Approval	**Projected End Date:**	Dec 2006

USA: Cost-Effectiveness Analysis of Assisted Reproductive Technology (FCO 174001)

Technical Monitor: RHoman
Collaborating Agency(s): Centers for Disease Control and Prevention (CDC)
Status: Ongoing
Group: HSR

USAID Intermediate Outcome: IR3 = Use of Contraceptives, Microbicides and Reproductive Health Technologies Optimized and Expanded

Objective(s): To model the costs and outcomes of assisted reproductive technologies as a function of the number of embryos transferred.

Description: As the success rate of assisted reproductive technology has improved, the risk and costs of poor birth outcomes associated with multiple birth pregnancies needs to be weighed with the lower success rate associated with fewer embryo transfers per transfer cycle. This subproject, funded through an Interagency Agreement with Centers for Disease Control and Prevention, uses decision analytic techniques to make the cost and effectiveness outcomes explicit to serve as a guide to the development of assisted reproductive technology recommendations and policies.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- CDC expressed their interest in applying FHI's cost effectiveness methodologies to an analysis of assisted reproductive health technologies. An Interagency Agreement was discussed as a potential funding mechanism to support this work.
- During the January-June 2006 time period, the interagency agreement was processed by CDC and USAID but there were no other activities.

Funding Source(s):	USAID - US Agency for International Development/OYB	**FCO Approved:**	Jun 2006
Total Approved Budget:	$ 25,739	**Projected End Date:**	Jan 2007

Worldwide: Information Resources Services (FCO 760/1067/119500)

Technical Monitor: BBarrows

Status: Ongoing
Group: EXEC

Objective(s): 1) To provide library information services to FHI staff, consultants, visitors, and subprojects; and 2) to assist in the dissemination of information on contraceptive and reproductive health research.

Description: This subproject supports the FHI Library, which provides information services to FHI staff, investigators, and others. Since 1989, the library has been fully automated, providing an integrated system of information management that combines acquisition, organization, and dissemination, with a growing emphasis on electronic access to and dissemination of research information. Since April 2001, the FHI library had been part of Field, Information and Training Services (FITS). In July 2004, the library was transferred to the Executive Office, and FCO 9987 was assigned to this activity. With the closure of the CTR Program, new FCO numbers were assigned to the library and the reporting functions for FCO 9987 were completed in August 2005. Until June 2006, FCO 119500 was financed with CRTU funds. The library is now funded out of the G&A, under FCO 1067, while FCO 760 continues to be a contribution from the HPTN group. Activities and accomplishments for FCO 1067 will not be routinely updated.

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Activities, Accomplishments, Problems between January 1, 2006—June 30, 2006

- This subproject was preliminarily established in July of 2005.
- A list of standardized subject headings and an authority file were delayed due to staff shortages.
- Library staff tracked news of FHI tenofovir trials for Senior Management.
- The report on impact factors for 2004 FHI publications was completed, distributed to staff and added to the library web page.
- A new Procite database on Avian flu was initiated and made available to staff.
- The Library newsletter, FYI, resumed a quarterly publication schedule.
- Revisions have started on the library web pages for easier navigation and more efficiency for users.

Findings and Outcomes:

- The library collection contains approximately 11,000 monographs and 800 journals and newsletter titles emphasizing contraception, family planning, sexually transmitted diseases, HIV/AIDS prevention, demography, statistics, and research methodology. It is one of the largest special libraries covering contraceptive and family planning research in the U.S. The library also houses special FHI databases on reproductive health topics and offers users access to more than 400 on-line database services.

Funding Source(s):		NIH - National Institutes of Health/NIH; USAID - US Agency for International Development/Core	**FCO Approved:**	**760**	Jun 2005
				119500	Jul 2005
				1067	May 2006
Total Approved Budget:	**760**	$ 15,000	**Projected End Date:**		Apr 2010
	119500	Annually Approved			
	1067	$ 158,592			
		$ 173,592			

APPENDIX A

Family Health International
List of CTR/CRTU – Supported Publications
September 1, 2005 – June 30, 2006

Appendix A

List of CTR/CRTU-Supported Publications
September 1, 2005- June 30, 2006

Since the August 2005 Contraceptive Technology and Family Planning Research Annual Report, FHI's Library has documented the publication of 37 new articles or other writings published, authored or coauthored by FHI staff and/or investigators, and supported—in whole or in part—by either the CTR or the CRTU. These publications serve to disseminate research results, synthesize what is known, and respond to current concerns regarding family panning and reproductive health. Final cost objective (FCO) numbers are provided following the citation to show first what funding supported time spent in writing the publication and secondly, if applicable, what funding supported the original research addressed by the article.

2005-53 Guest G, Bunce A, Johnson L, Akumatey B, Adeokun L. Fear, hope, and social desirability bias among women at high risk for HIV in West Africa. *J Fam Plann Reprod Health Care* 2005 Oct; 31 (4): 285-7. (FCO-9501) (FCO-9501)

2005-56 Haydon A, Olawo A. A new look at IUDs. *Health Work Matter* 2005 Aug; 1 (2): 3. (FCO-3007)

2005-57 Mack N; Woodsong C; MacQueen K; Guest G; Namey E. *Qualitative research methods: a data collector's field guide.* RTP, NC: Family Health International; 2005. 118 p. (FCO-9398) (FCO-9398)

2005-59 Grimes DA, Lopez L, Raymond EG, Halpern V, Nanda K, Schulz KF. Spermicide used alone for contraception. *Cochrane Database Syst Rev* 2005 Oct 19; (4): CD005218, 21 p. (FCO-5206)

2005-60 Lopez LM, Grimes DA, Schulz KF. Nonhormonal drugs for contraception in men: a systematic review. *Obstet Gynecol Surv* 2005 Nov; 60 (11): 746-52. (FCO-5206)

2005-64 Barnhart KT, Pretorius ES, Shaunik A, Timbers K, Nasution M, Mauck C. Vaginal distribution of two volumes of the novel microbicide gel cellulose sulfate (2.5 and 3.5 mL). *Contraception* 2005 Jul; 72 (1): 65-70. (FCO-1737/9101) (FCO-1737)

2005-65 Trussell J, Dominik R. Will microbicide trials yield unbiased estimates of microbicide efficacy? *Contraception* 2005 Dec; 72 (6): 408-13. (FCO-9113)

2005-66 Morrison CS, Turner AN, Curtis K, Bright P, Blumenthal PD. Chapter 11, Highly-effective contraception and sexually transmitted infections in the Western European context. In: Glasier A; Wellings K; Critchley H, editors. *Contraception and contraceptive use.* London: RCOG Press; 2005; p 119-35. (FCO-5352/1387)

2005-68 Stanback J, Diabate F, Dieng T, Duarte de Morales T, Cummings S, Traoré M. Ruling out pregnancy among family planning clients: the impact of a checklist in three countries. *Stud Fam Plann* 2005 Dec; 36 (4): 311-5. (FCO-9304) (FCO-9312/9381)

2005-72 González MI, Chen-Mok M. El número deseado de hijos en Costa Rica: 1993-1999.

In: Arley RC, editor. *Población y salud en Mesoamérica.* San José, Costa Rica: Centro Centroamericano de Población; 2005. p. 135-47. (FCO-9100)

2005-73 Choe MK, Thapa S, Mishra V. Early marriage and early motherhood in Nepal. *J Biosoc Sci* 2005 Mar; 37 (2): 143-62. (FCO-9304) (FCO-7403/7412)

2005-79 Tawye Y, Jotie F, Shigu T, Ngom P, Maggwa N. The potential impact of community-based distribution programmes on contraceptive uptake in resource-poor settings: evidence from Ethiopia. *Afr J Reprod Health* 2005 Dec; 9 (3): 15-26. (FCO 9484) (FCO 9484)

2005-80 Sokal DC, Blithe D, Gabelnick H. The future of male contraception. In: Donta B; Vogelsong KM; Van Look PF; Puri CP. *Enhancing male partnership in sexual and reproductive health.* Mumbai, India: National Institute for Research in Reproductive Health; 2005. 93-101. (FCO-2000)

2005-81 Severy L. Sexual and reproductive needs of men worldwide. In: Donta B; Vogelsong KM; Van Look PF; Puri CP. *Enhancing male partnership in sexual and reproductive health.* Mumbai, India: National Institute for Research in Reproductive Health; 2005. 29-35. (FCO-9396)

2006-01 Steiner MJ, Hylton-Kong T, Figueroa JP, Hobbs MM, Behets F, Smikle M, Tweedy K, Powell S, McNeil L, Brathwaite A. Does a choice of condoms impact sexually transmitted infection incidence? A randomized controlled trial. *Sex Transm Dis* 2006 Jan; 33 (1): 31-5. (FCO-2254) (FCO-2254)

2006-02 Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991 to 1999. *Am J Obstet Gynecol* 2006 Jan; 194 (1): 92-4. (FCO-5352)

2006-03 Tolley EE, Severy LJ. Integrating behavioral and social science research into microbicide clinical trials: challenges and opportunities. *Am J Public Health* 2006 Jan; 96 (1): 79-83. (FCO-9506)

2006-05 Mauck CK, Weiner DH, Creinin MD, Archer DF, Schwartz JL, Pymar HC, Ballagh SA, Henry DM, Callahan MM. FemCap™ with removal strap: ease of removal, safety and acceptability. *Contraception* 2006 Jan; 73 (1): 59-74. (FCO-9102) (FCO-9109)

2006-06 Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods* 2006 Feb; 18 (1): 59-82. (FCO-9501) (FCO-9501)

2006-07 Stanback J, Nakintu N, Qureshi Z, Nasution M. Does assessment of signs and symptoms add to the predictive value of an algorithm to rule out pregnancy? *J Fam Plann Reprod Health Care* 2006 Jan; 32 (1): 27-9. (FCO-9304) (FCO-9344)

2006-08 Grant RM, Moore JP, Clarke E, Lama JR, Cates W Jr, Coates T, Cohen MS, Delaney M, Wainberg MA, Levy V, McConnell J, MacQueen KM. HIV research and access to treatment (authors' response). *Science* 2006 Jan 13; 311 (5758): 175-6.

2006-09 Severy LJ. Contraception. In: Salkind, NJ, editor. *Encyclopedia of human development, Vol. 1.* Thousand Oaks, CA: Sage Publications; 2006; 306-8. (FCO-9396)

2006-10 Halpern V, Grimes DA, Lopez L, Gallo MF. Strategies to improve adherence and acceptability of hormonal methods for contraception. *Cochrane Database Syst Rev*

2006; (1): CD004317, 24 p. (FCO-5206 / 172002 / 112112)

2006-12 McCarraher DR, Martin SL, Bailey PE. The influence of method-related partner violence on covert pill use and pill discontinuation among women living in La Paz, El Alto and Santa Cruz, Bolivia. *J Biosoc Sci* 2006 Mar; 38 (2): 169-86. (FCO-6352)

2006-16 Beksinska M, Smit J, Mabude Z, Vijayakumar G, Joanis C. Performance of the Reality® polyurethane female condom and a synthetic latex prototype: a randomized crossover trial among South African women. *Contraception* 2006 Apr; 73 (4): 386-93. (FCO-N/A) (FCO-2286)

2006-17 Ulin PR; Robinson ET; Tolley EE. *Investigación aplicada en salud pública: métodos cualitativos.* Washington DC: Pan American Health Organization; 2006; 286 p. (FCO-3205)

2006-18 Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight. *Cochrane Database Syst Rev* 2006 Jan 25; (1): CD003987, 72 p. (FCO-5206 / 172002 / 112112)

2006-19 Gallo MF, Grimes DA, Lopez LM, Schulz KF. Non-latex versus latex male condoms for contraception. *Cochrane Database Syst Rev* 2006 Jan 25; (1): CD003550, 96 p. (FCO-5206 / 172002 / 112112)

2006-21 Edelman A, Gallo MF, Nichols MD, Jensen JT, Schulz KF, Grimes DA. Continuous versus cyclic use of combined oral contraceptives for contraception: systematic Cochrane review of randomized controlled trials. *Hum Reprod* 2006 Mar; 21 (3): 573-8. (FCO-112112)

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APPENDIX B

Subprojects
by
Region/Country and Current FCO(s)

AFRICA

Africa Regional

Assessing Provision of Family Planning and Reproductive Health Services in Commercial Sector HIV/AIDS Programs	124102

Ghana

Evaluation of Integrating Family Planning into ART Services in Ghana	124101

Kenya

Assessing the Future Role of Implants	112122
Building Strategic Information Capacity within NASCOP	153102
Evaluating the Young Men as Equal Partners" Project	114100
Examining the Family Planning Needs of Women Traditionally Targeted for HIV/STI Services	124100
Improving Use of Family Planning in VCT	14104/153103
Kenya Division of Reproductive Health Capacity Development: Follow-on Activity	143103
Kenya Field Support Management	143100
Kenya IUD Revitalization - Transition Phase and M & E	113111
Kenya Information Management: Hormonals & HIV	143102
Kenya PEPFAR Management	153106
Kenya: Enhanced Country Program Implementation	113122
Kenya: Evaluation of What's New & Cool for Youth Booklet	143101
Risk of HIV and Feasibility Research Among House Girls in Nairobi	154100

Madagascar

Evaluating Disinhibition of Condom Use in a Diaphragm Trial	112115

Nigeria

Evidence-based Child Spacing Intervention Development for Northern Nigeria	143104
Nigeria: Rapid Programmatic Assessment for FP/VCT Integration	113105
Operations Research: Male Motivators Promoting Family Planning in the Nigeria Police Force	114109
Randomized Controlled Trial of Cellulose Sulfate (CS) Gel and HIV in Nigeria	2266/132100
Savvy Phase III RCT, Nigeria	2277/132104

South Africa

ABC Approach for Youth on University Campuses in South Africa	153101
Acidform Behavioral Data Analysis	116101
Developing and Testing Interventions to Serve the Family Planning Needs of PMTCT Clients in South Africa	114103
Enhancing PMTCT Performance in South Africa	153104
Feasibility of Randomized Trial to Evaluate the Effect of DMPA on STI	112119
Improving Continuation Rates for Injectable Contraceptives-South Africa	114102
RCT of Tenofovir Gel in South Africa	132108
Safety and Feasibility of the Diaphragm Used with ACIDFORM	2276/112103
South Africa Advance Account	113101
South Africa: Enhanced Country Program Implementation	13123/133100
South Africa: Microbicides: Carraguard Phase III Trial Interim Analysis for DSMB	139100
Strengthening Linkages between FP, HBC and ARV Services	153105

Uganda

Improving Service Delivery of CBD of DMPA in Uganda	114111
Operations Research: Staged Training of Private Sector Midwives to Increase IUD Use	114108
Promoting DMPA Provision by Community Health Providers	113108
Repositioning Family Planning: Revitalizing LAPMs	113110
Uganda: Enhanced Country Program	113125

ASIA/NEAR EAST

India

Discontinuation of DMPA among Private Sector Clients in India	12031/114110
Vasectomy Acceptability among Clients and Providers in Uttar Pradesh	116100

EUROPE

Switzerland

WHO Technical Assistance - Sarah Johnson	119505
WHO Technical Assistance - Shawn Malarcher	114112

LATIN AMERICA

Nicaragua

Improving Continuation Rates for Injectable Contraceptives-Nicaragua	114113

NORTH AMERICA

USA

Assessment of Soluble and Cellular Markers of Inflammation after Vaginal Product Use	132109
BASS Management	116102
CRTU: Hormonals Strategy Group	112121
CTR End-of-Project & CRTU Project Launch Meeting	113120
Choice of Condoms on Incident STI	2254/112116
Comparative Study of PATH's Soft-Cling Woman's Condom and the Female Condom	2287/112102
Contraceptive Discontinuation: Setting the CRTU Research Agenda	113102
Coordination and Statistical Support of CONRAD Activities	112100
Cost-Effectiveness Analysis of Assisted Reproductive Technology	174001
Development of a Phase II Microbicide Trial Protocol	132107
Female Condom Reuse: Assessing the Efficacy of Dish Detergent in Removing HIV and Chlamydia from the Surfaces of Inoculated FC2 Female Condoms	132115
Formative Research to Determine the Feasibility of Recruitment for True Efficacy" Trials	116104
MRI Studies of New Microbicide Formulations	132112
Male Tolerance Study of UC-781 Gel	132111
Meeting on Pregnancy in Microbicide Studies	132106/172001
Microbicide Database, Phase I, Social & Scientific Systems, Inc. (SSS)	139500
New Delivery Device for Vaginal Microbicides	1844/2290/132103
Next Steps for Clinical Research of New Female Condoms	112111/132114
Phase I Study of the BufferGel Duet's Functional Performance, Safety and Acceptability	2292/132102
Pivotal Effectiveness Study of the PATH SILCS Diaphragm	2299/112101
Regulatory Affairs and Quality Assurance for the CRTU	119200
Safety and Acceptability of Citric Acid	2295/132110
Statistical Support - Microbicides	139101
Structural Integrity of the FC2 Female Condom	112117

WORLD

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BIOS Technical Leadership	119100
Barrier Method Strategy Development	119503
CRD Management	112000
CRD Technical Leadership	112120

Worldwide - continued

CRTU Executive Management	119502
CRTU Knowledge Management	113118
CRTU Monitoring and Evaluation	119501
CRTU Network of Champions	113113
Cochrane Fertility Regulation Review Group, 2005-2010	12112/172002
Data Management Division Management	119400
FHI Publications Revenue	113271
Follow-Up: Sharing Information on HIV and Hormonal Contraception with Global Audiences	113119
Global Advocacy & Stakeholder Engagement for LAPMs	113109
Global Consultation on Female Condom	113100
HIV and Contraceptive Services Strategy Group	119504
HSR Technical Leadership	114106
Implementing Best Practices Consortium	113116
Independent Monitoring of CONRAD Collaborative Studies	2285/132101
Information Resources Services	760/1067/119500
Inter-Laboratory Trials	118104
International Standards Development	118100
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Maximizing Access and Quality (MAQ) IUD Subcommittee, and FHI's IUD Checklist Production and Dissemination	113112
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Microbicide Strategy Group	139102
Pregnancy Provider Checklist & Reference Guide 2005 Update & Implementation	113107
Production Surveillance - Domestic Procurement - OCs, IUDs, Injectables, etc.	148102
Production Surveillance - Offshore Procurement - OCs, IUDs, Injectables, etc.	148103
Production Surveillance of Condoms- Domestic and Off-Shore	148100
Production Surveillance, Domestic and Off-Shore, for Hormonal and Long-acting and Permanent Methods	148101
Providing Global Leadership to Family Planning and HIV Integration Efforts	113104/123100
Research to Practice Leadership	113114
Scale-up and Global Dissemination of Kenya's FP/VCT Integration Package	113126/123102
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Technical Oversight Committee	118103

Worldwide - continued

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Tool Kit to Increase Access to Appropriate and Effective Contraception for Clients with HIV	113106
USAID Best Practices Package: Development and M & E	113115/123101

APPENDIX C

ADVISORY COMMITTEE ROSTERS

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